US010543019B2

(12) **United States Patent**
Erickson

(10) **Patent No.: US 10,543,019 B2**
(45) **Date of Patent: Jan. 28, 2020**

(54) **EXTERNAL FIXATION**

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(73) Assignee: **Zimmer, Inc.**, Warsaw, IN (US)

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(21) Appl. No.: **15/892,704**

(22) Filed: **Feb. 9, 2018**

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Related U.S. Application Data

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(51) **Int. Cl.**
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A61B 50/33 (2016.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/6416*** (2013.01); ***A61B 17/6425*** (2013.01); ***A61B 17/6458*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC . A61B 17/6491; A61B 17/6483; A61B 17/66; A61B 17/6475; A61B 17/6466; A61B 17/6458; A61B 17/64; A61B 17/60
See application file for complete search history.

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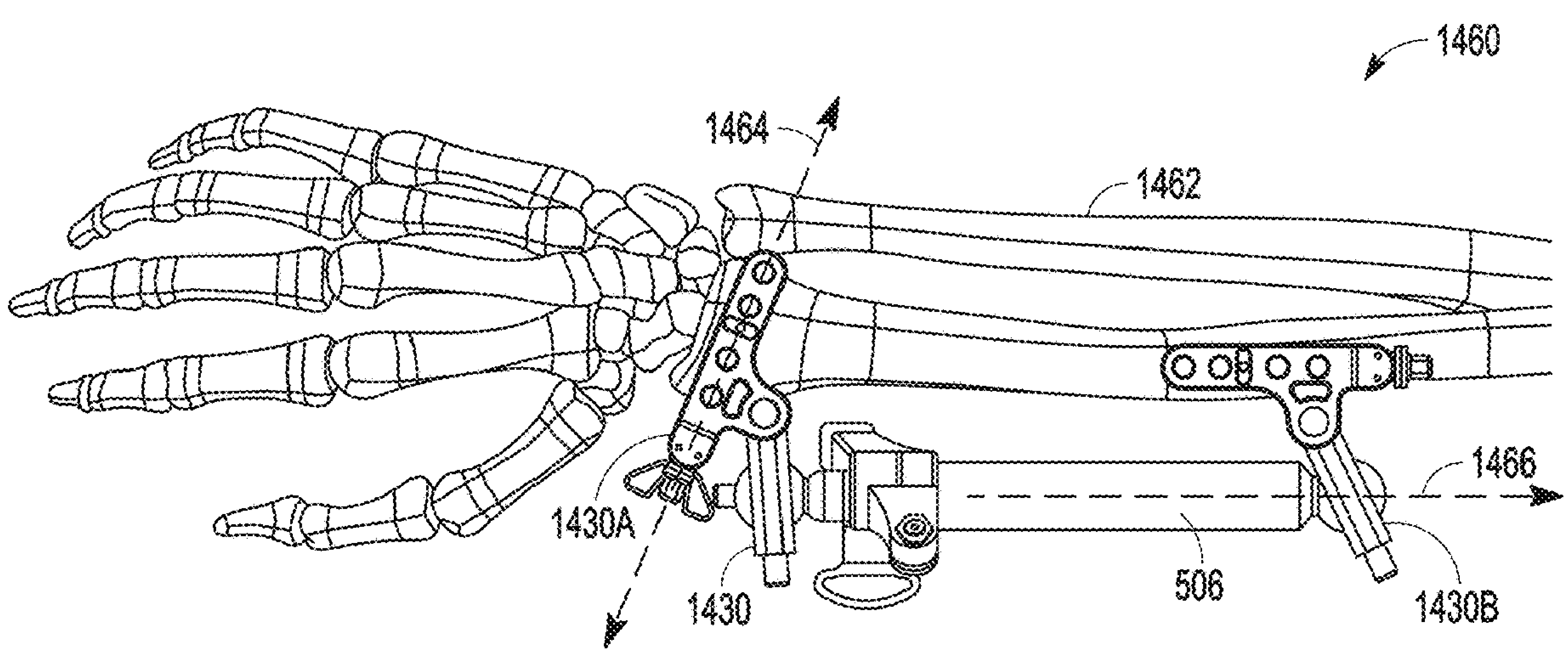
(74) *Attorney, Agent, or Firm* — Schwegman Lundberg & Woessner, P.A.

(57) **ABSTRACT**

External fixation systems, and methods for immobilizing joints or fractured bones. An external fixation system may include one or more clamp assemblies connected to one or more rod assemblies at polyaxial joints. Each rod assembly may be length adjustable, and may include a one-way locking mechanism to provisionally lock the length of the rod assembly, and additional locking mechanisms to permanently lock the length of the rod assembly. The system may be deployed pre-assembled as a unit to immobilize a joint or fracture. Another external fixation system further includes a spanning member extending transverse to the rod assemblies. Two or more external fixation systems may be deployed in a stacked configuration on one set of bone pins to immobilize two joints and/or fractures. The systems may be provided in kits including guiding instrumentation, bone pins and pin clamping assemblies for connecting the bone pins to the external fixation systems.

20 Claims, 45 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 14/456,407, filed on Aug. 11, 2014, now Pat. No. 9,924,969.

(51) **Int. Cl.**
A61B 50/24 (2016.01)
A61B 50/00 (2016.01)
A61B 50/30 (2016.01)

(52) **U.S. Cl.**
CPC ***A61B 50/24*** (2016.02); ***A61B 50/33*** (2016.02); *A61B 17/645* (2013.01); *A61B 2050/0065* (2016.02); *A61B 2050/3008* (2016.02)

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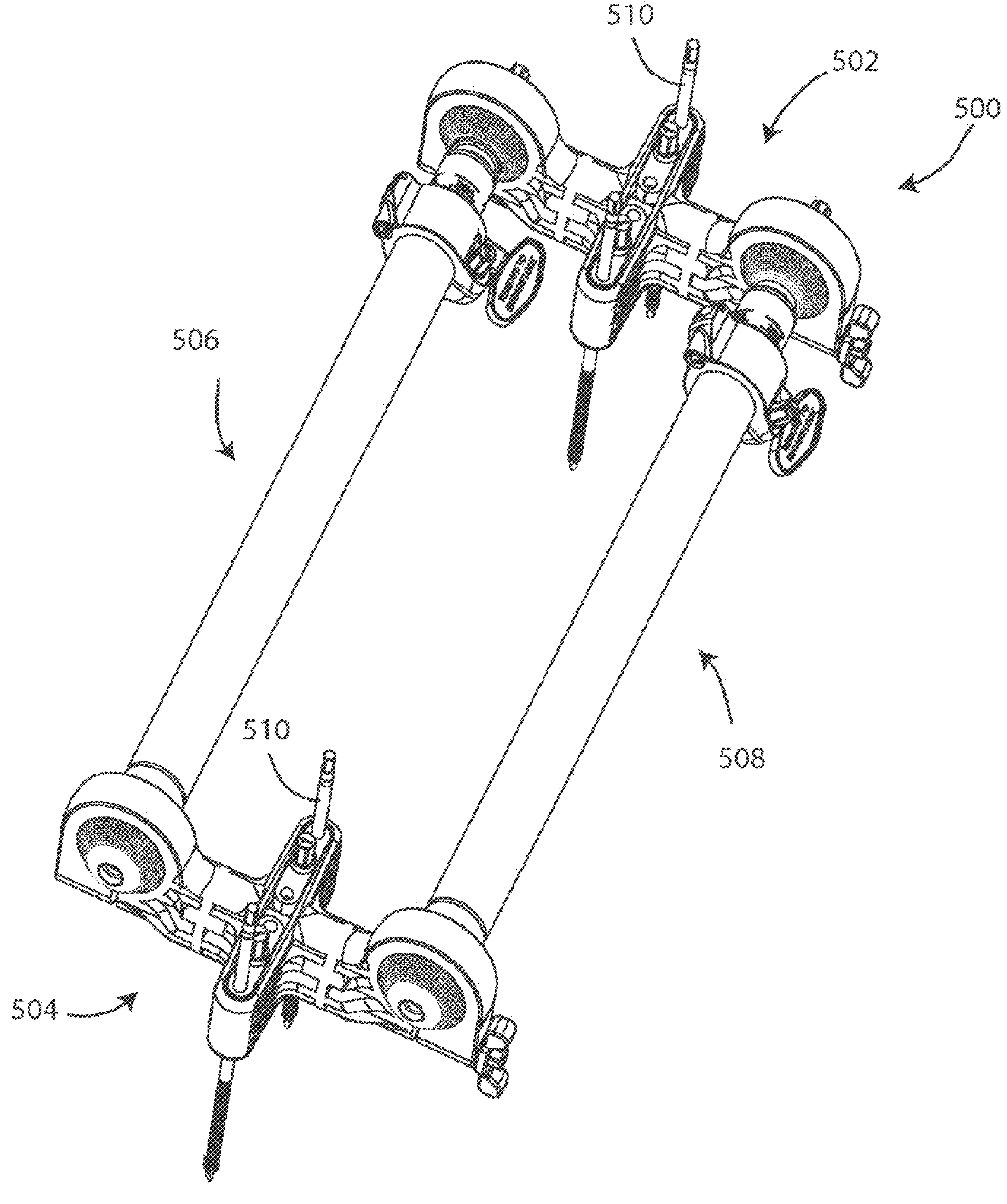

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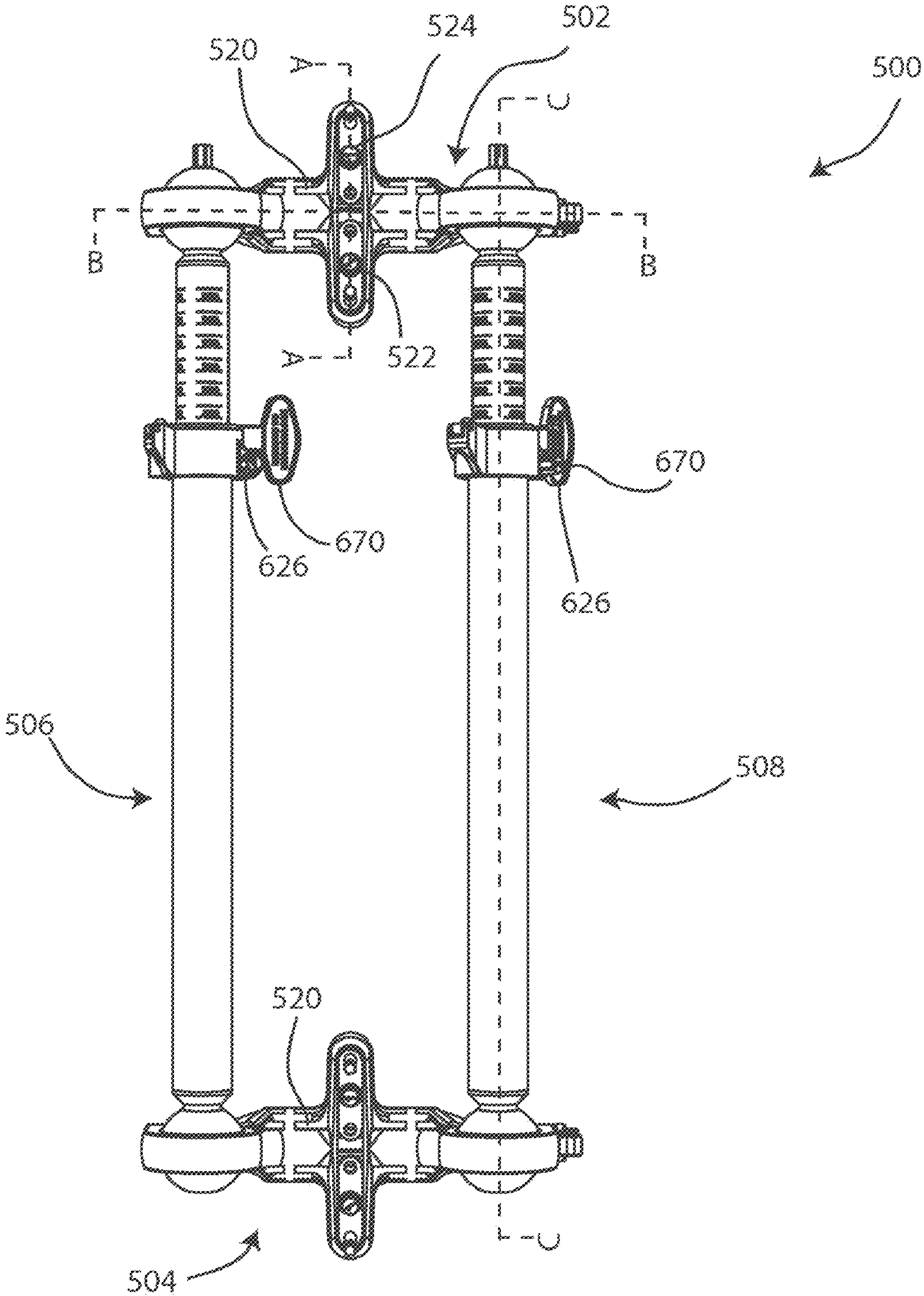

FIG. 2

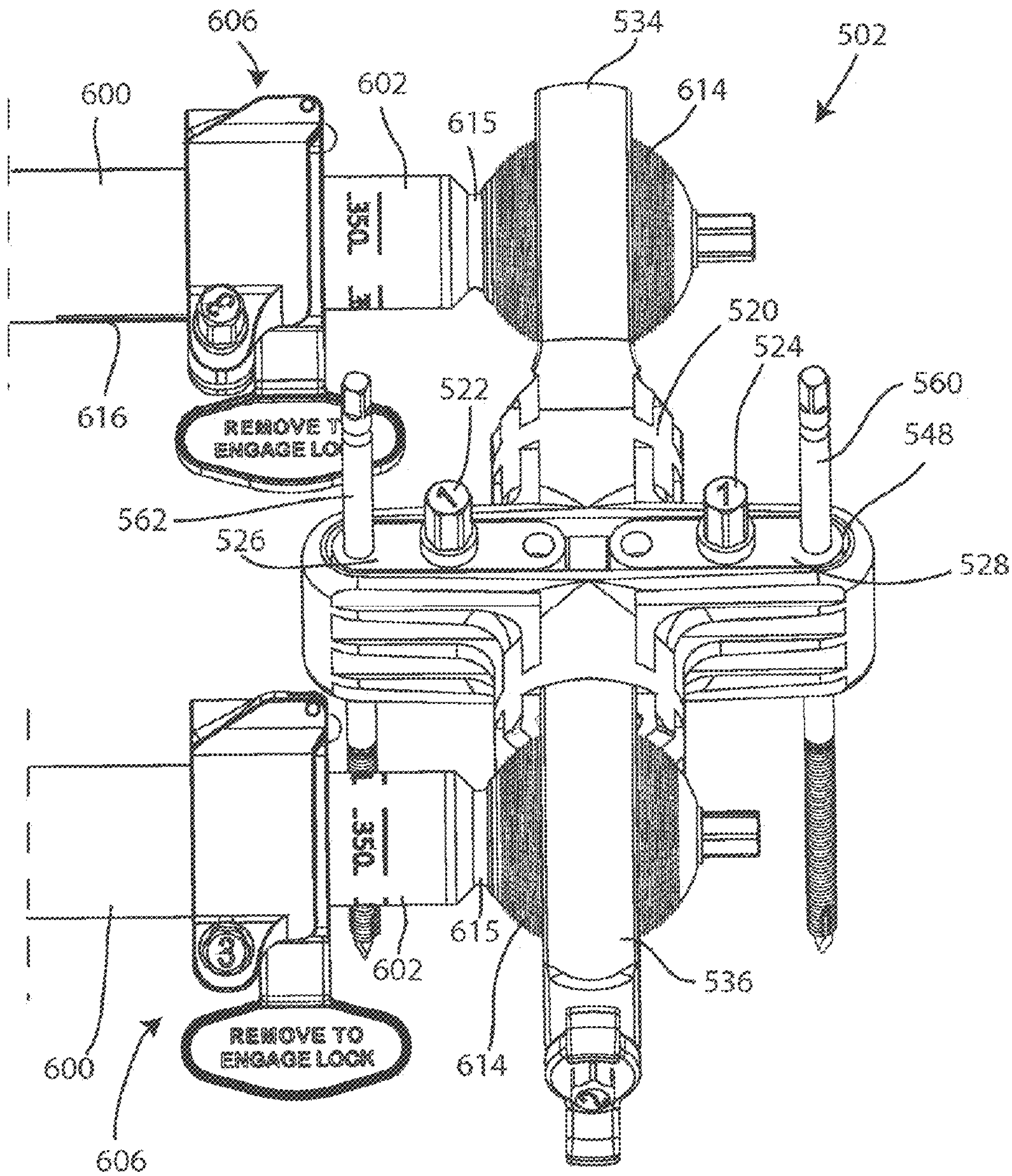
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FIG. 3

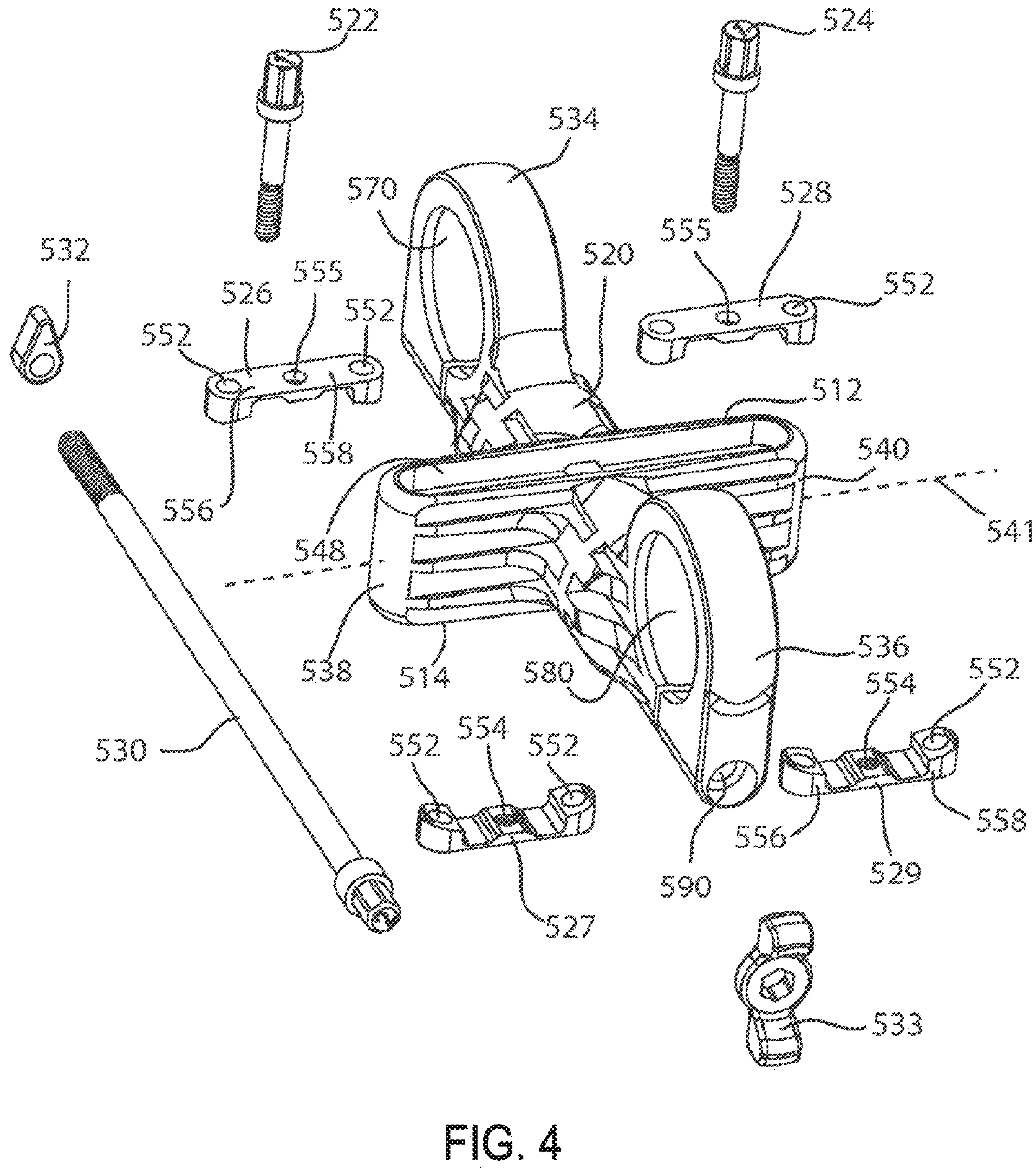
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FIG. 4

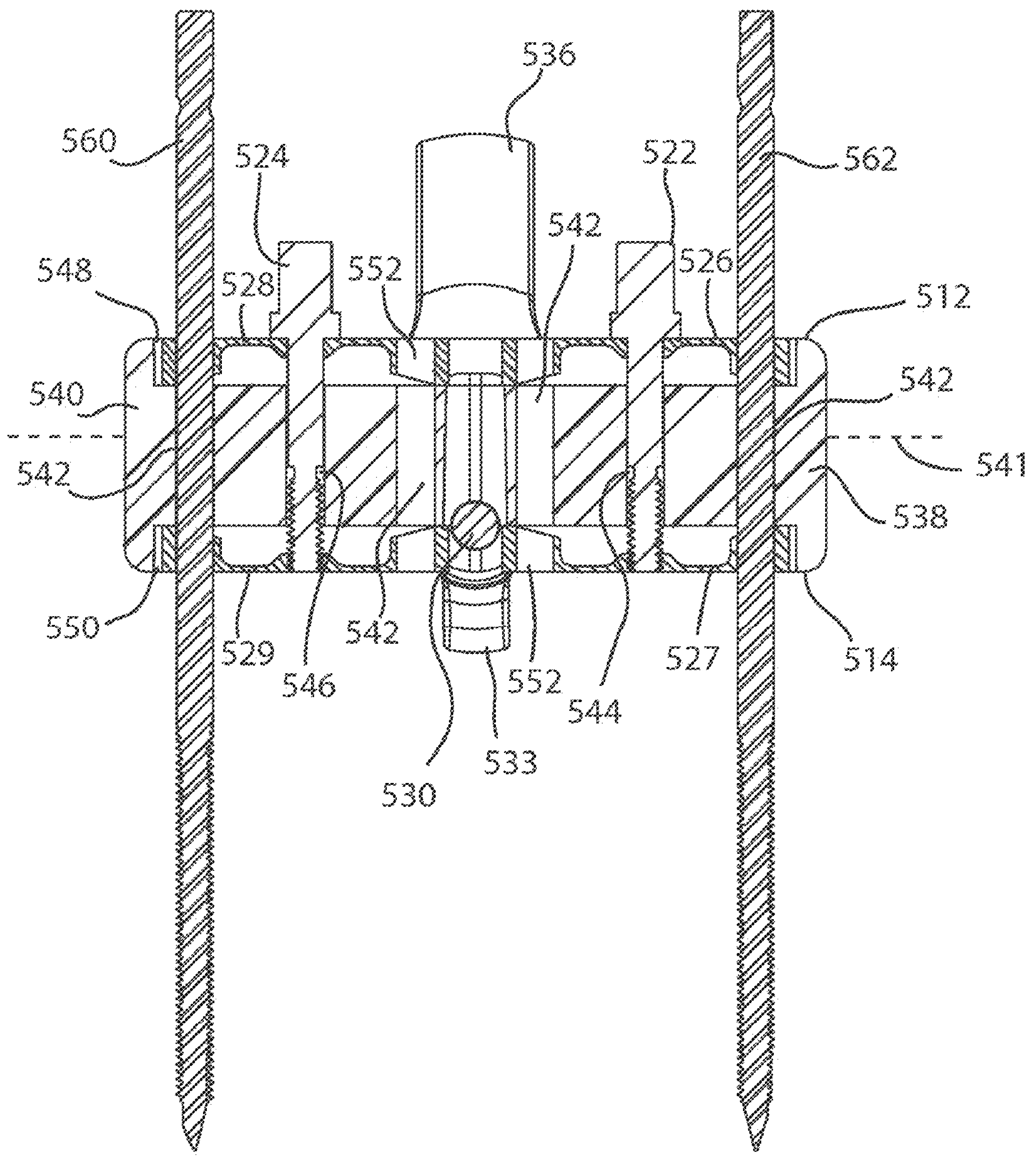
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FIG. 5

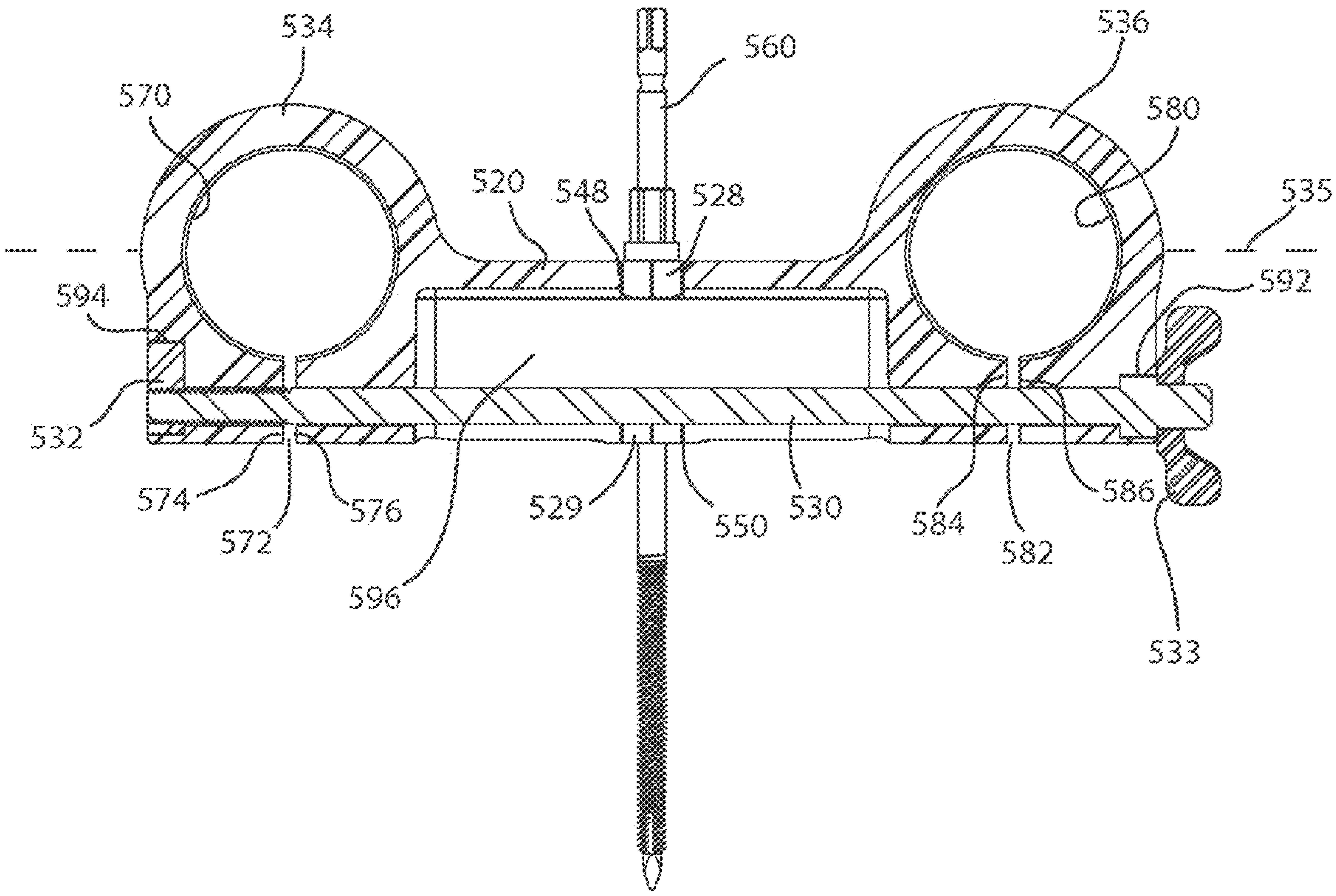
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FIG. 6

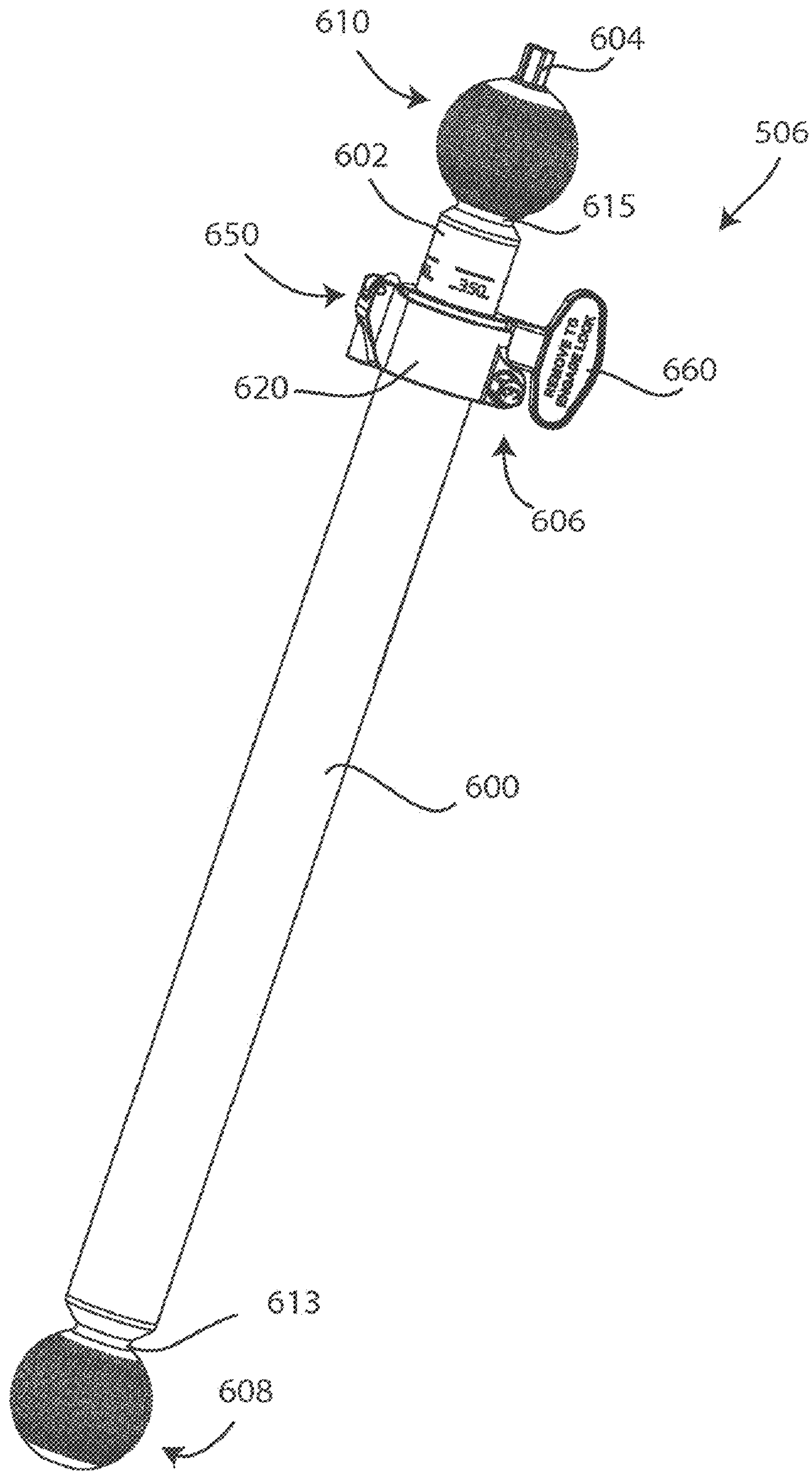

FIG. 7

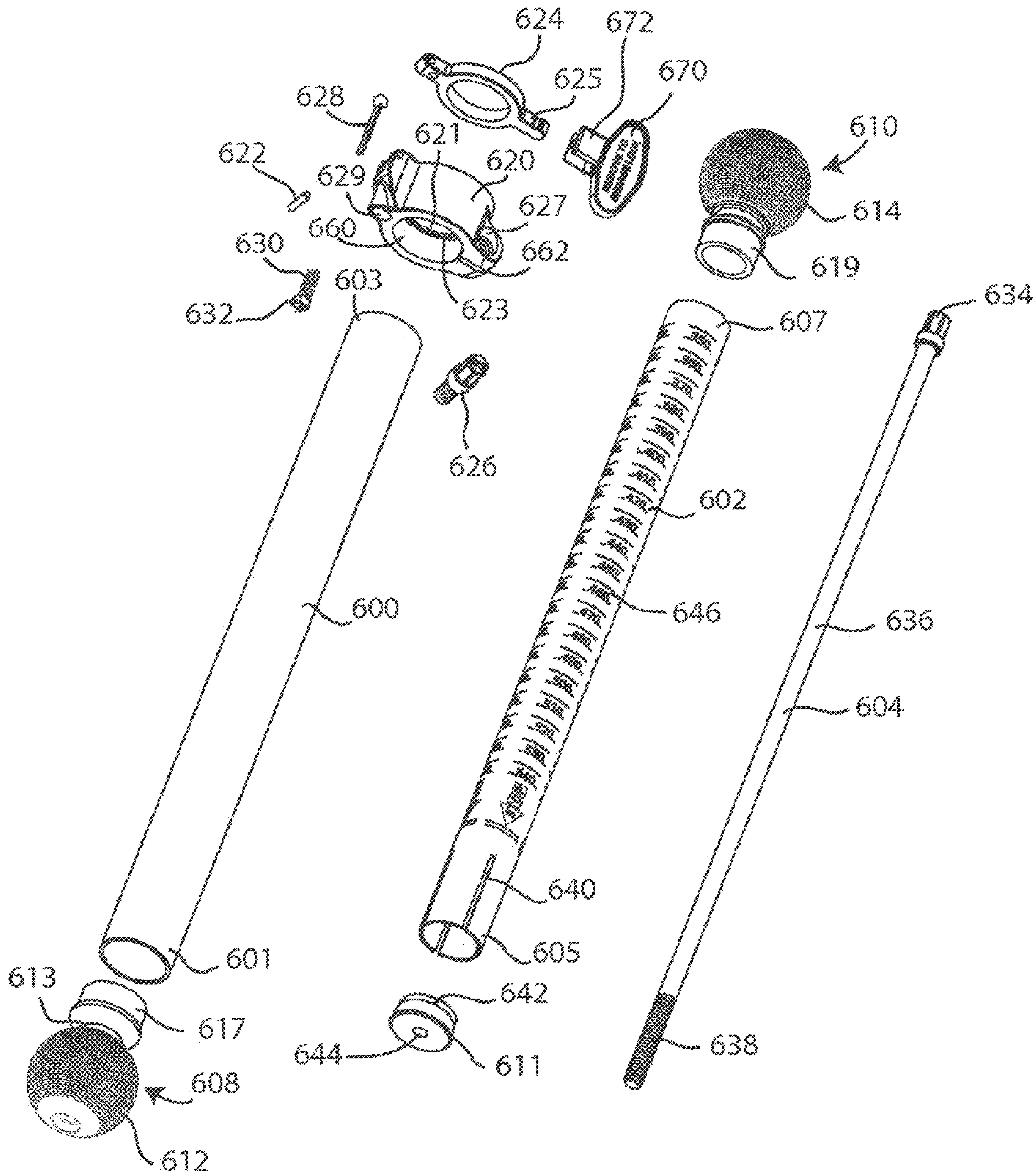
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FIG. 8

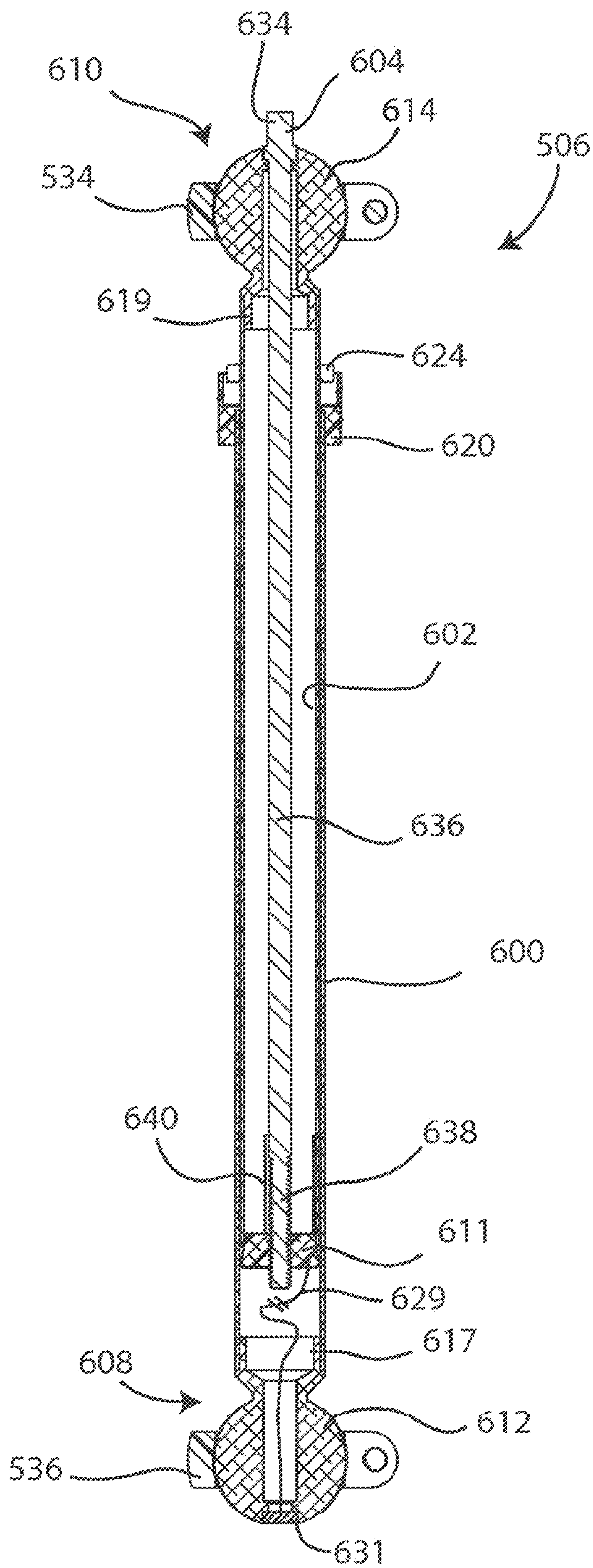
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FIG. 9

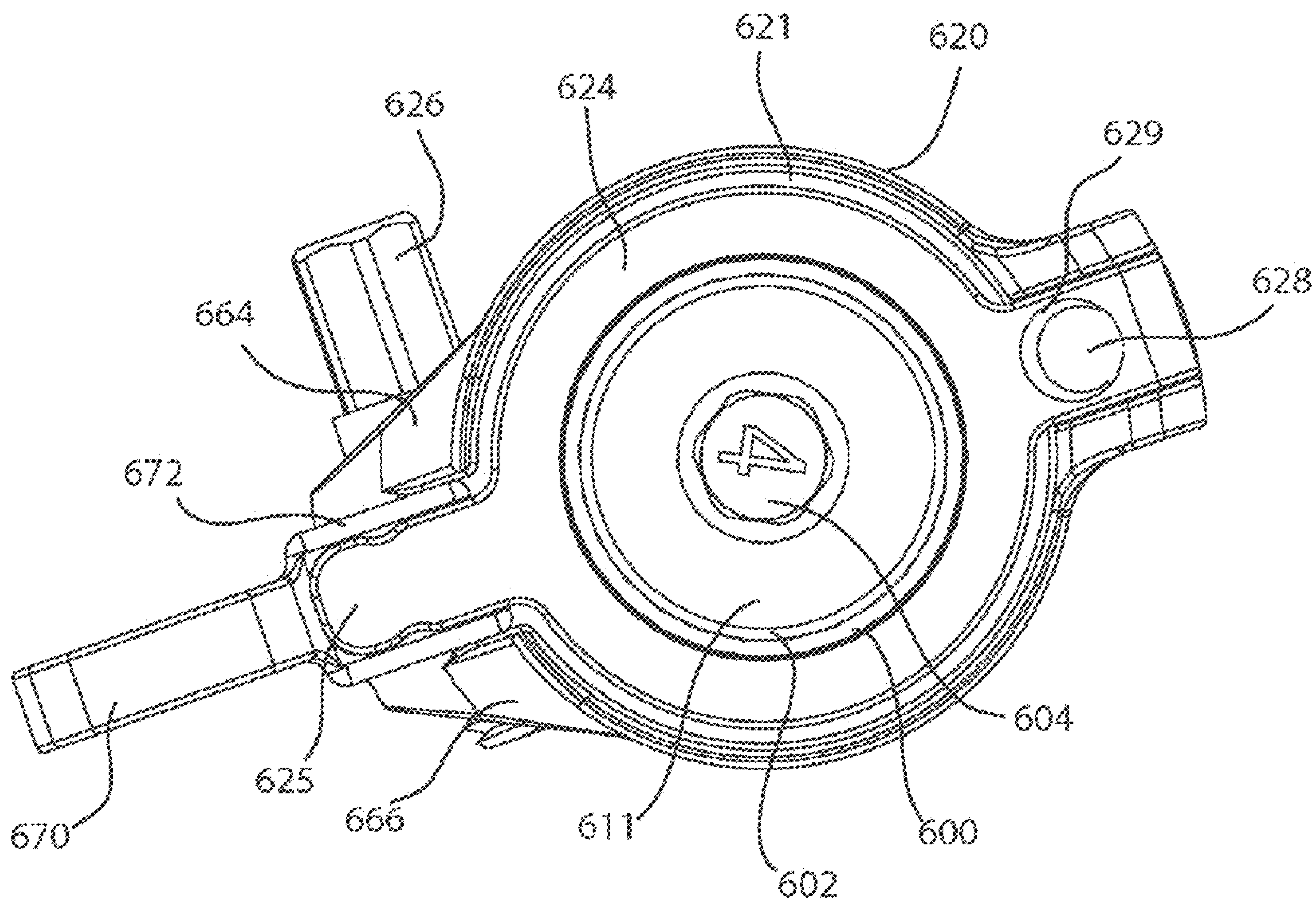

FIG. 10

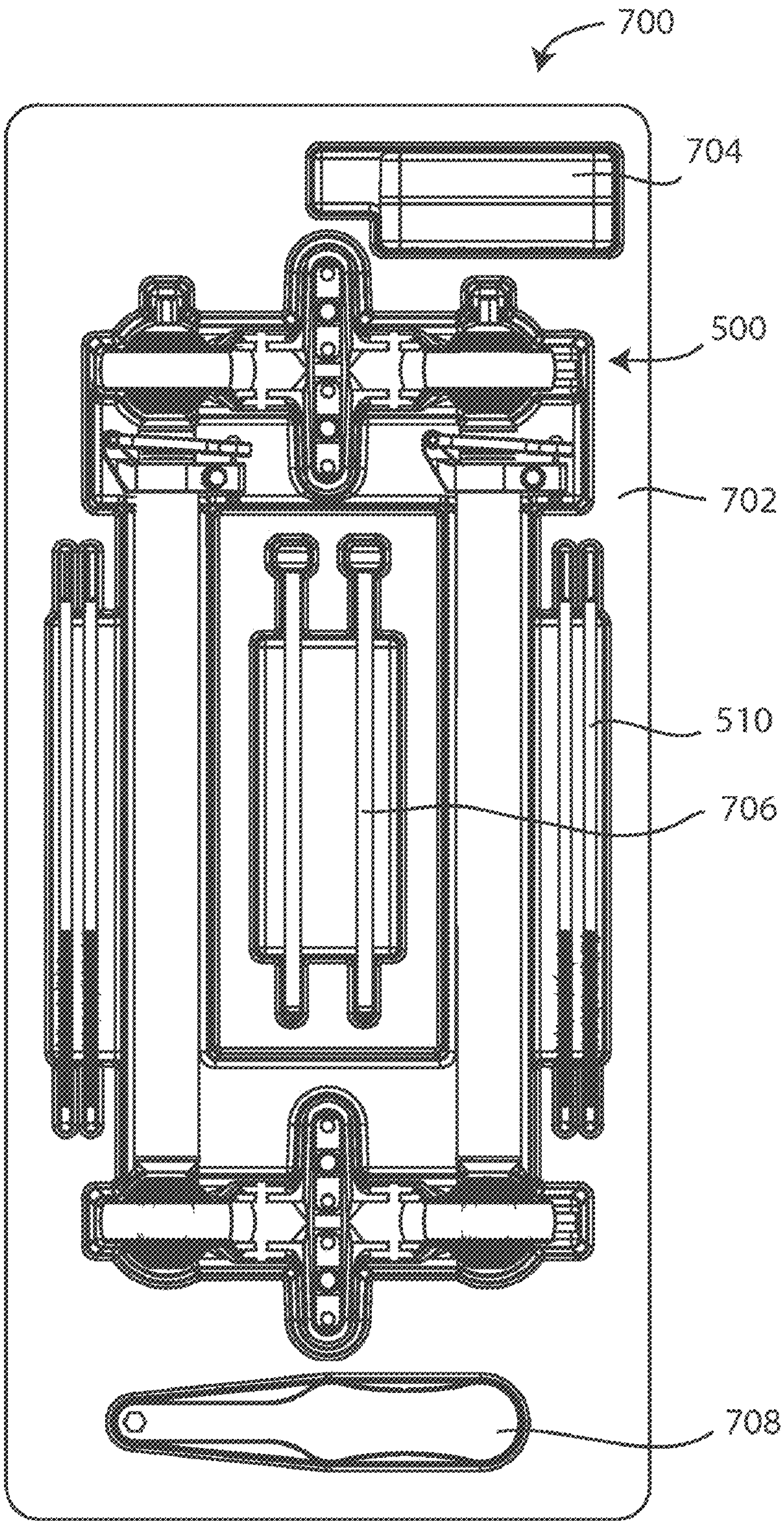

FIG. 11

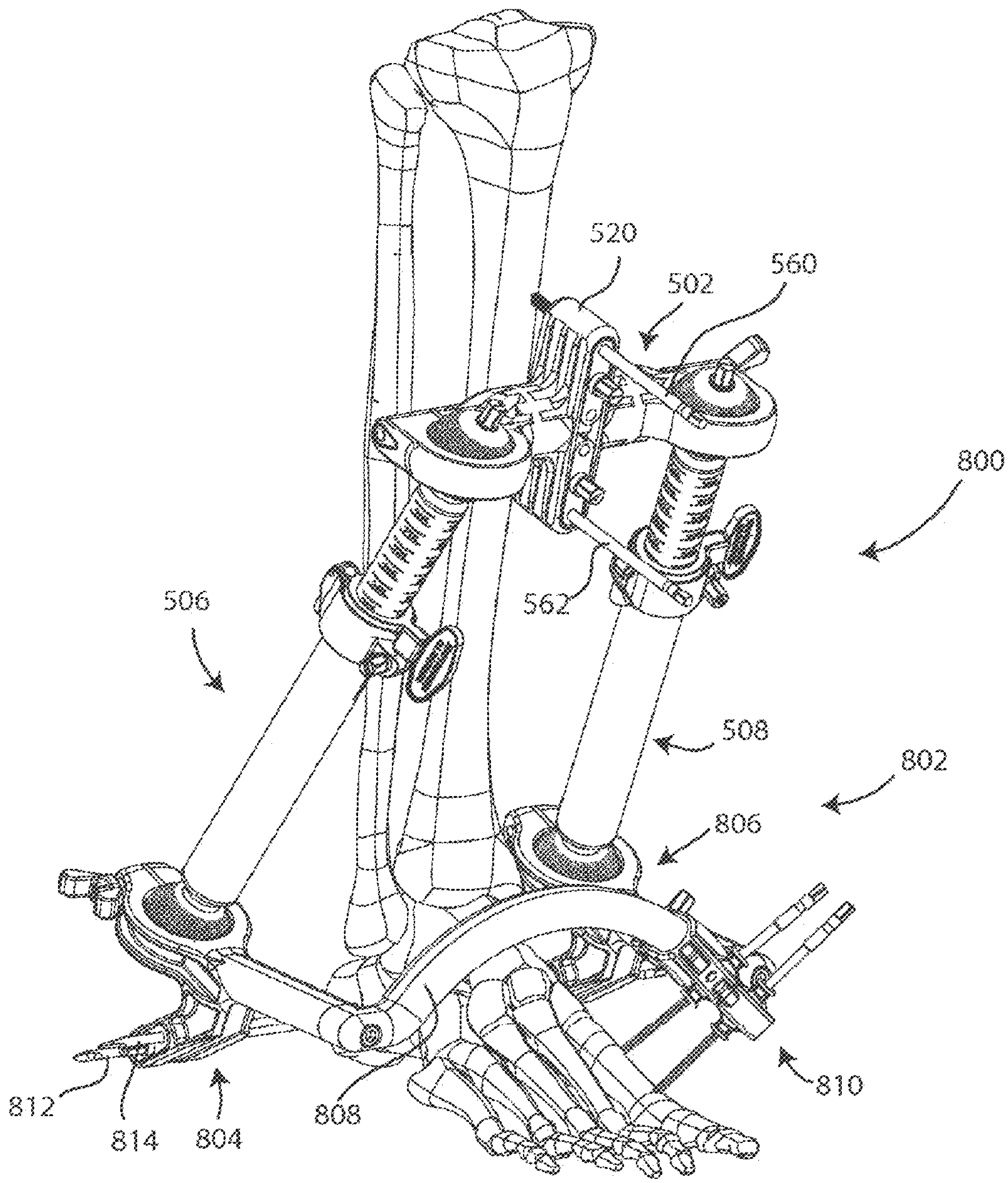

FIG. 12

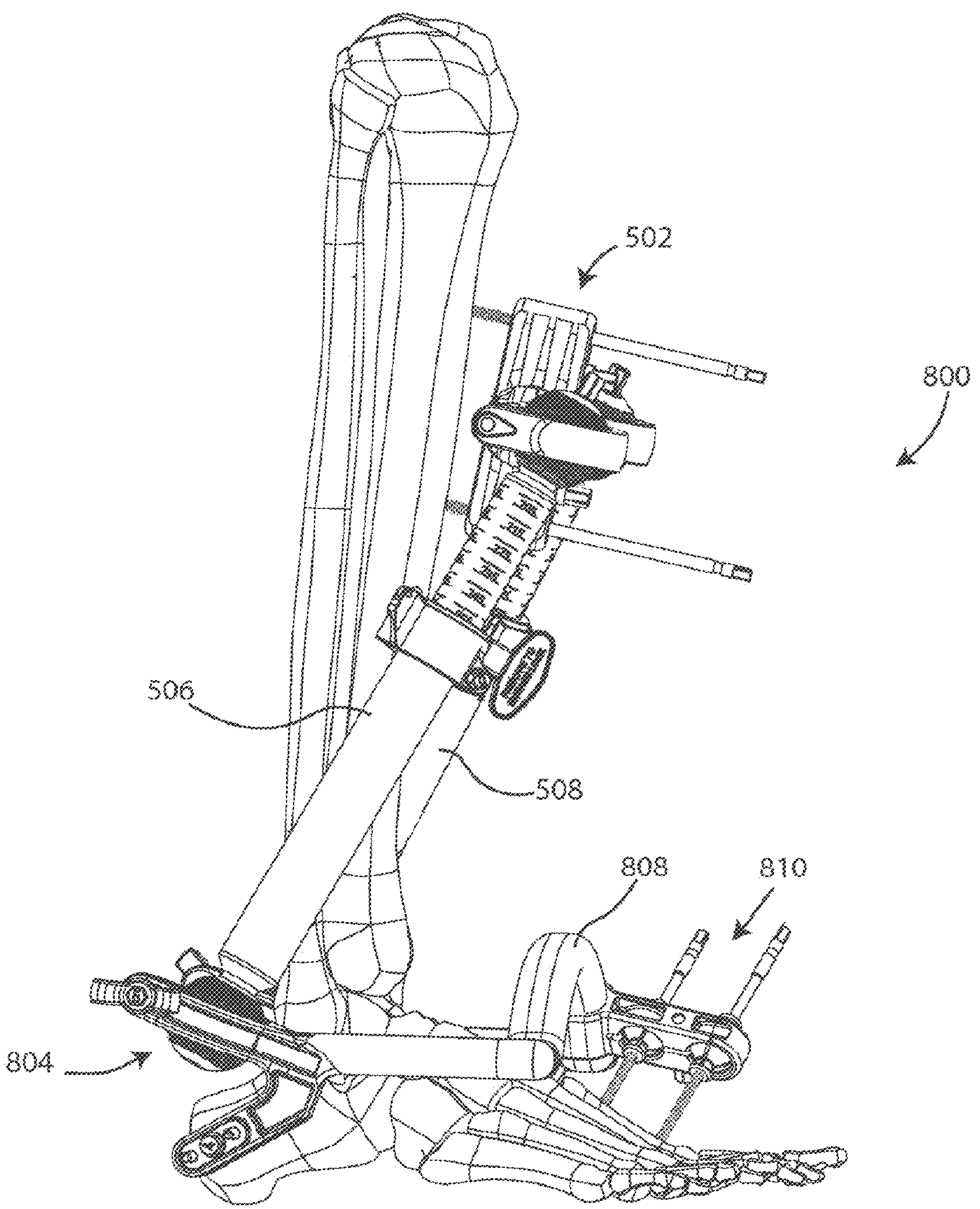

FIG. 13

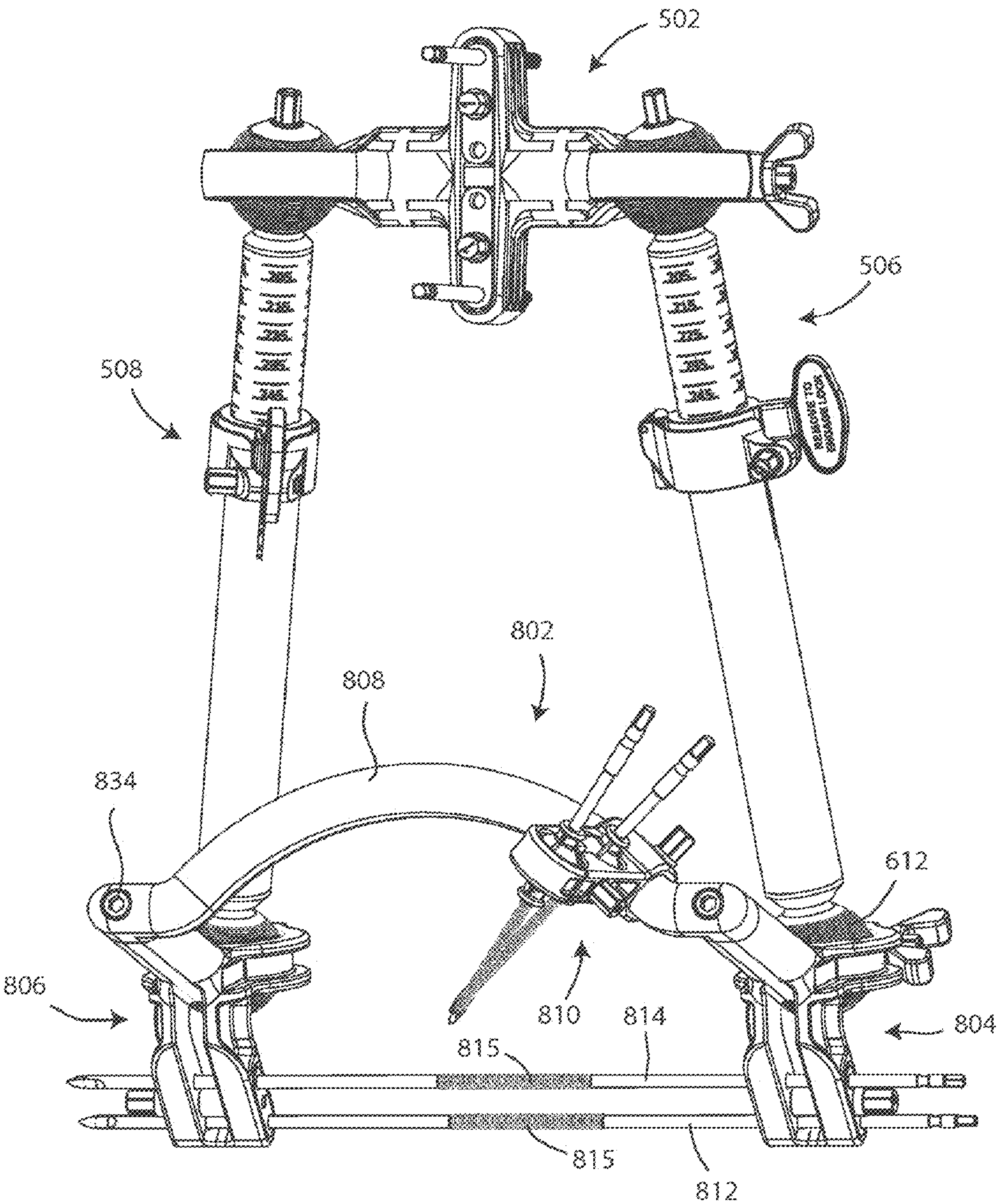

FIG. 14

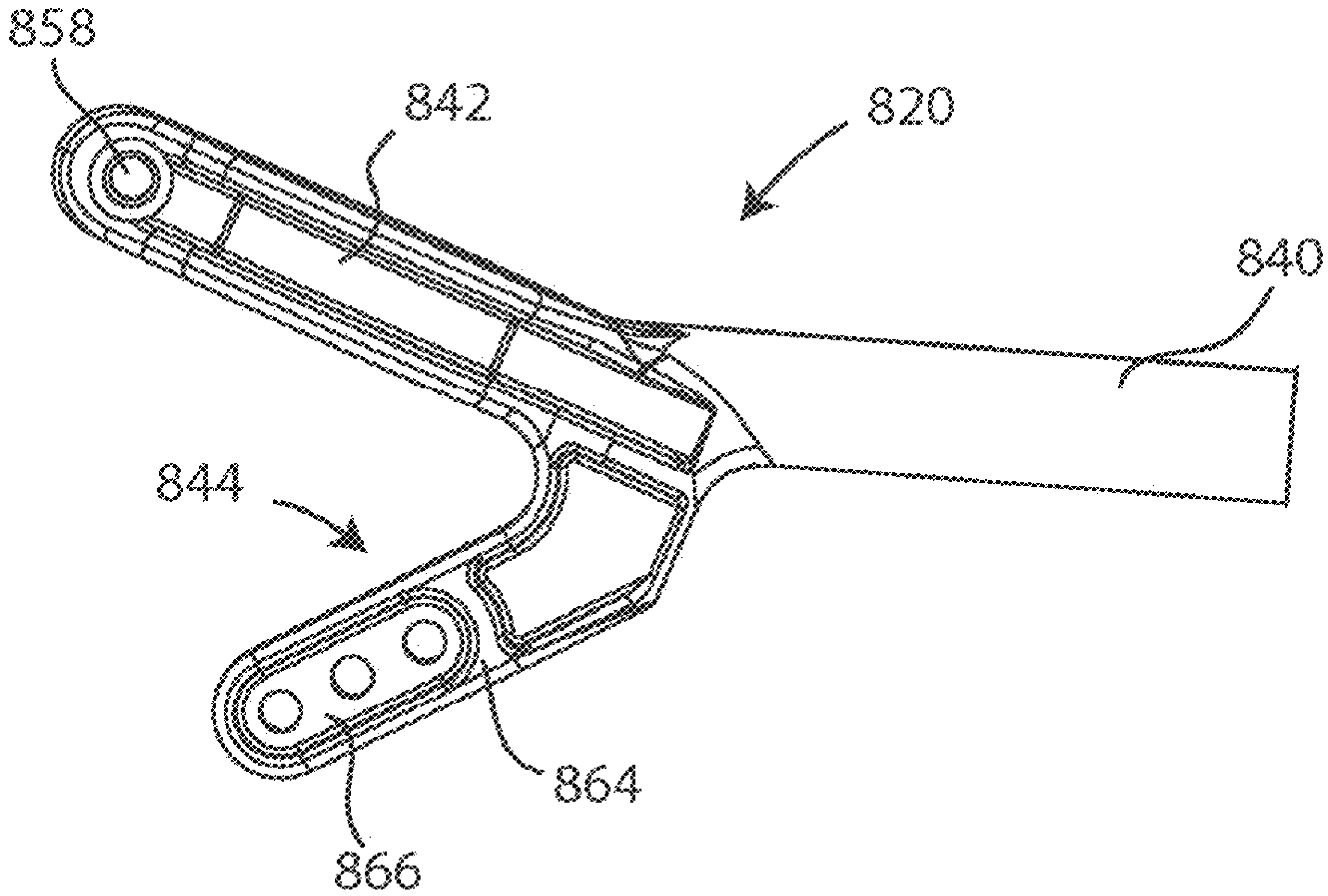

FIG. 15A

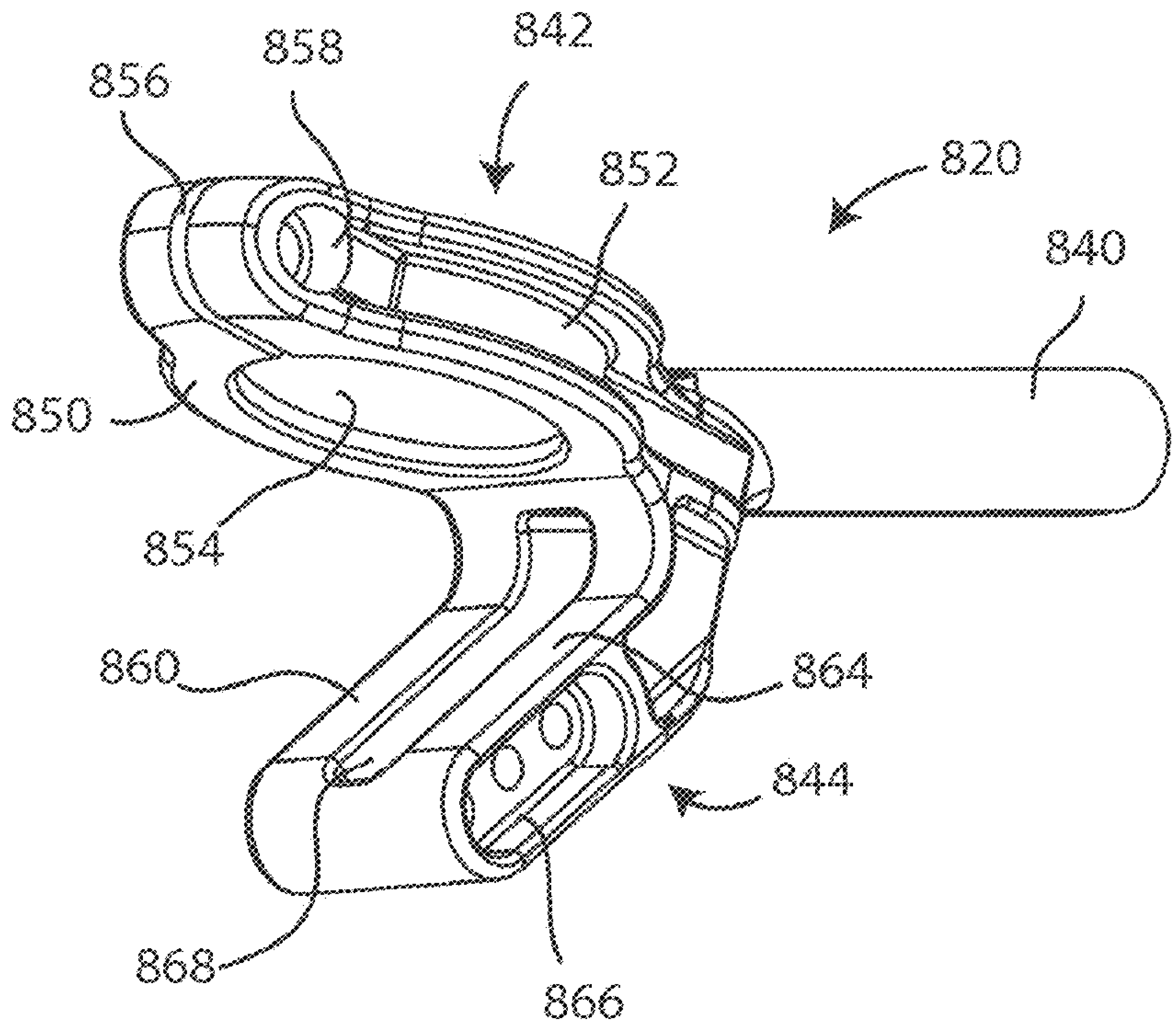

FIG. 15B

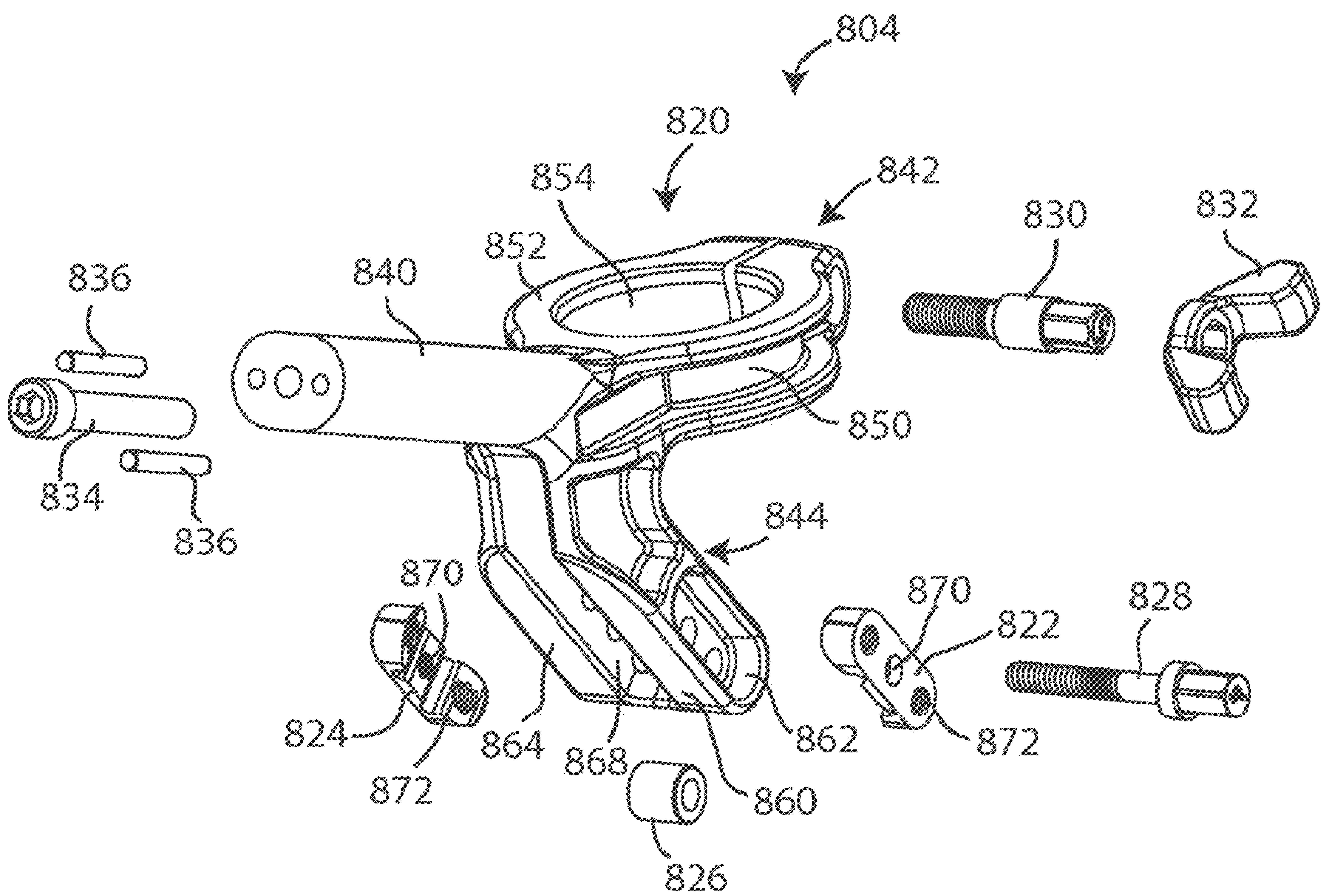
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FIG. 16

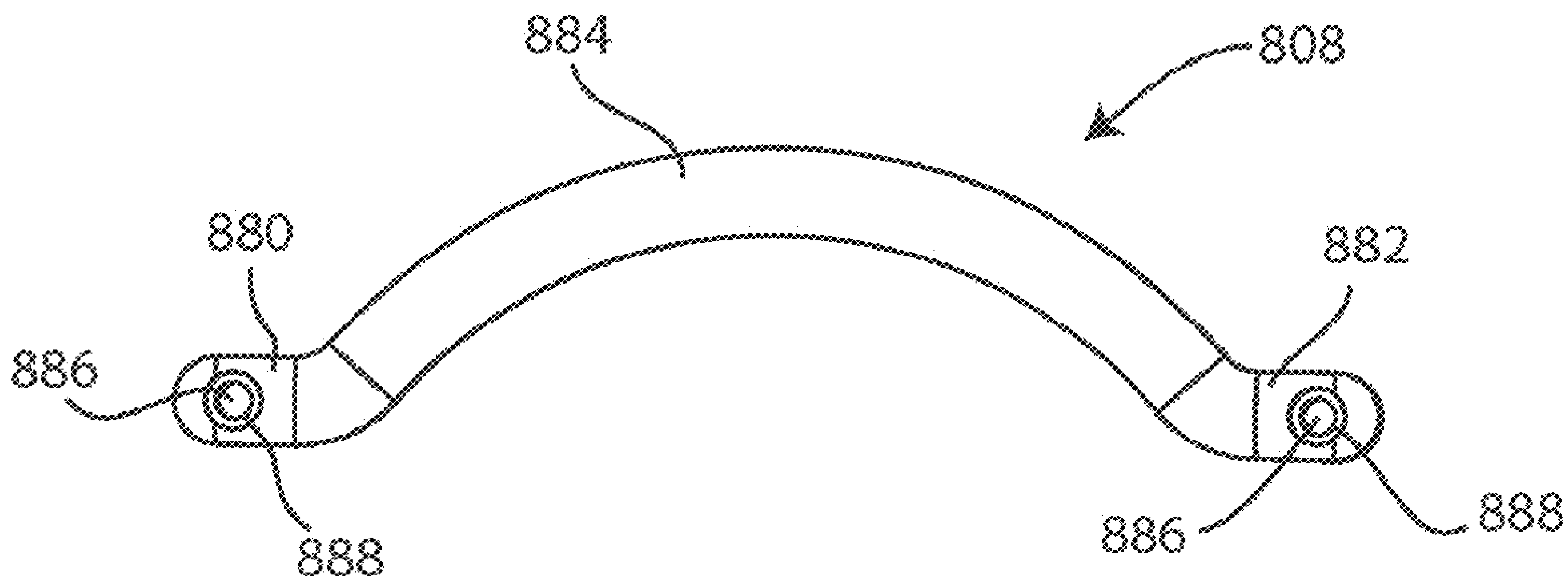


FIG. 17A

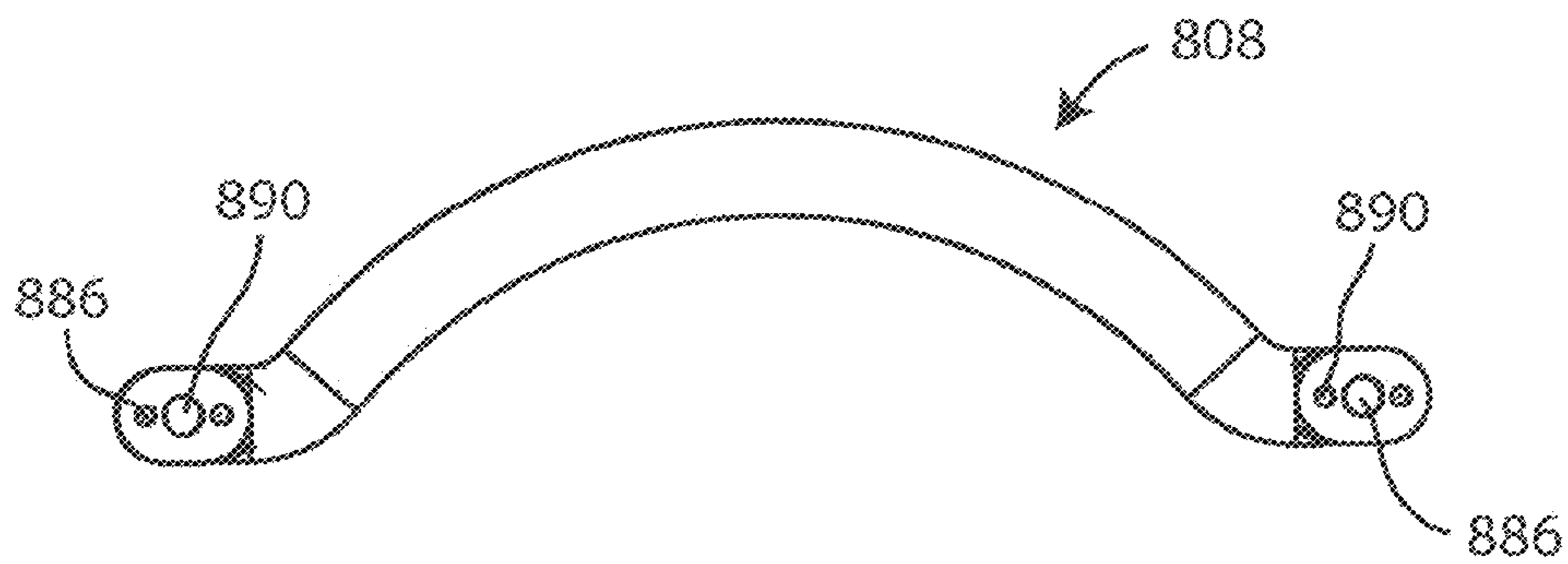


FIG. 17B

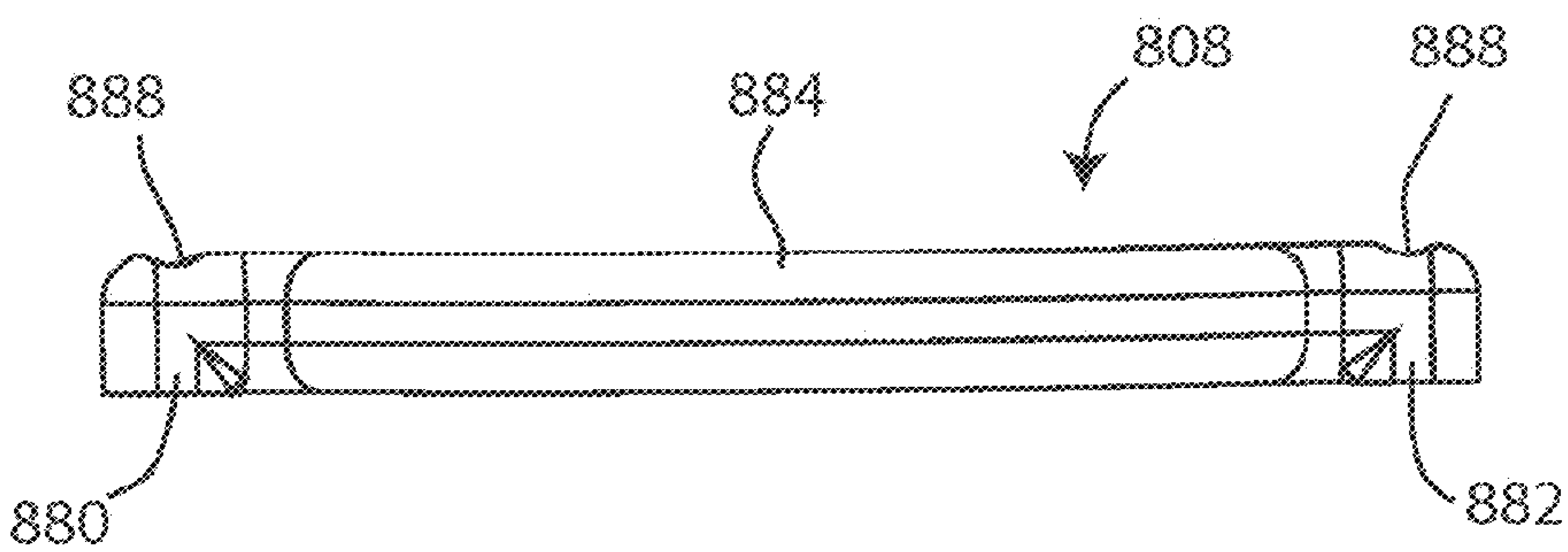


FIG. 17C

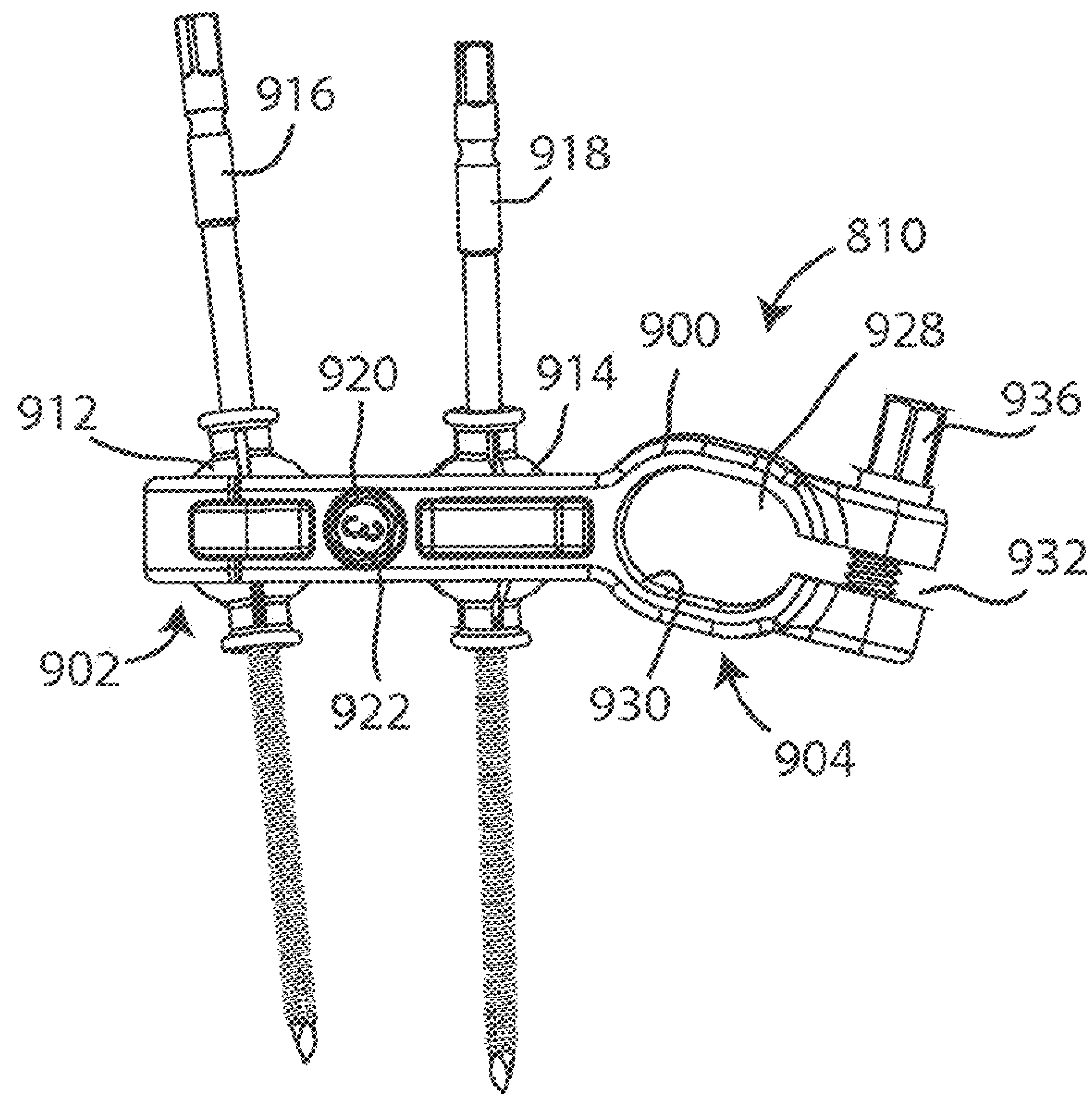


FIG. 18A

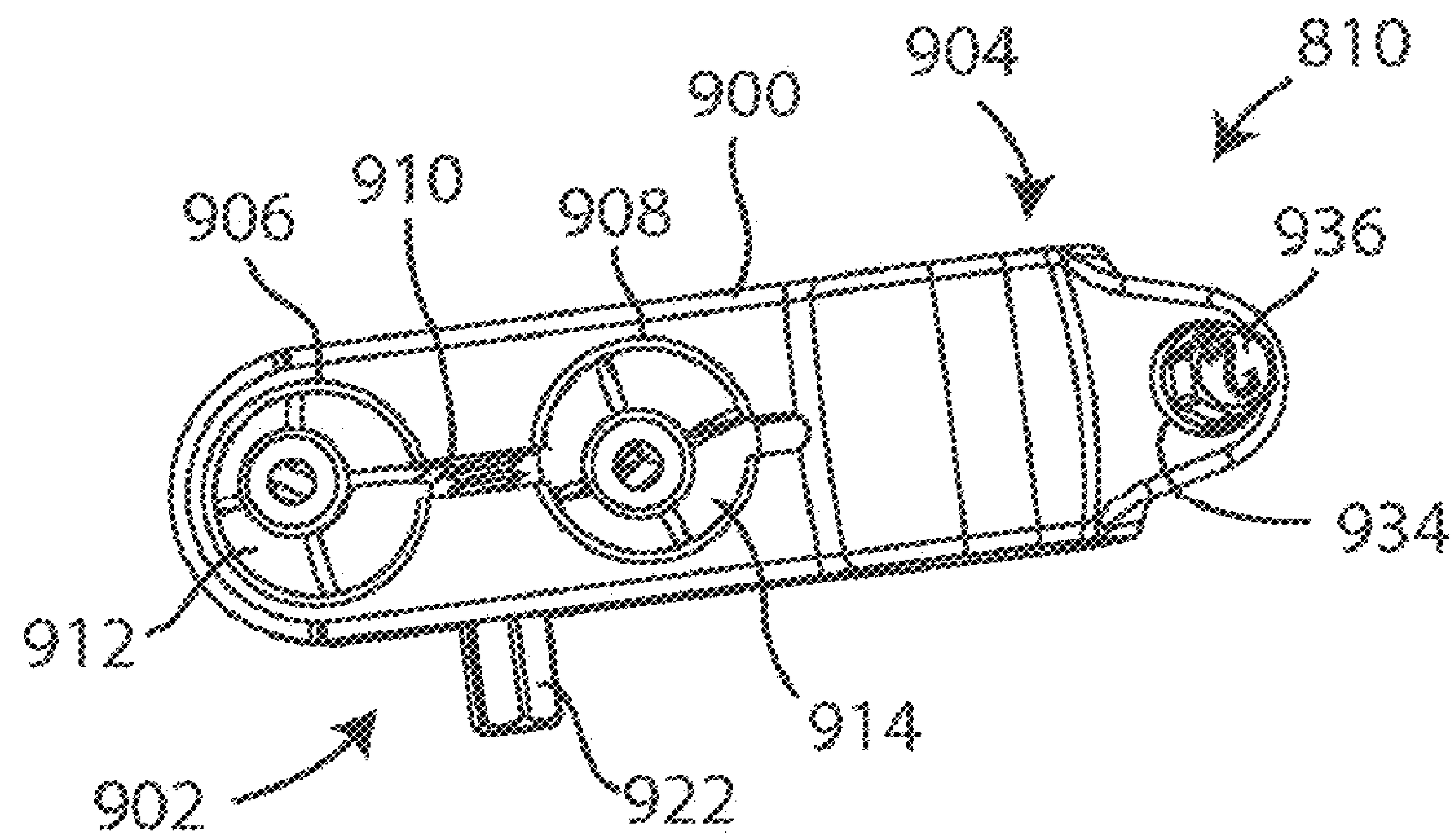


FIG. 18B

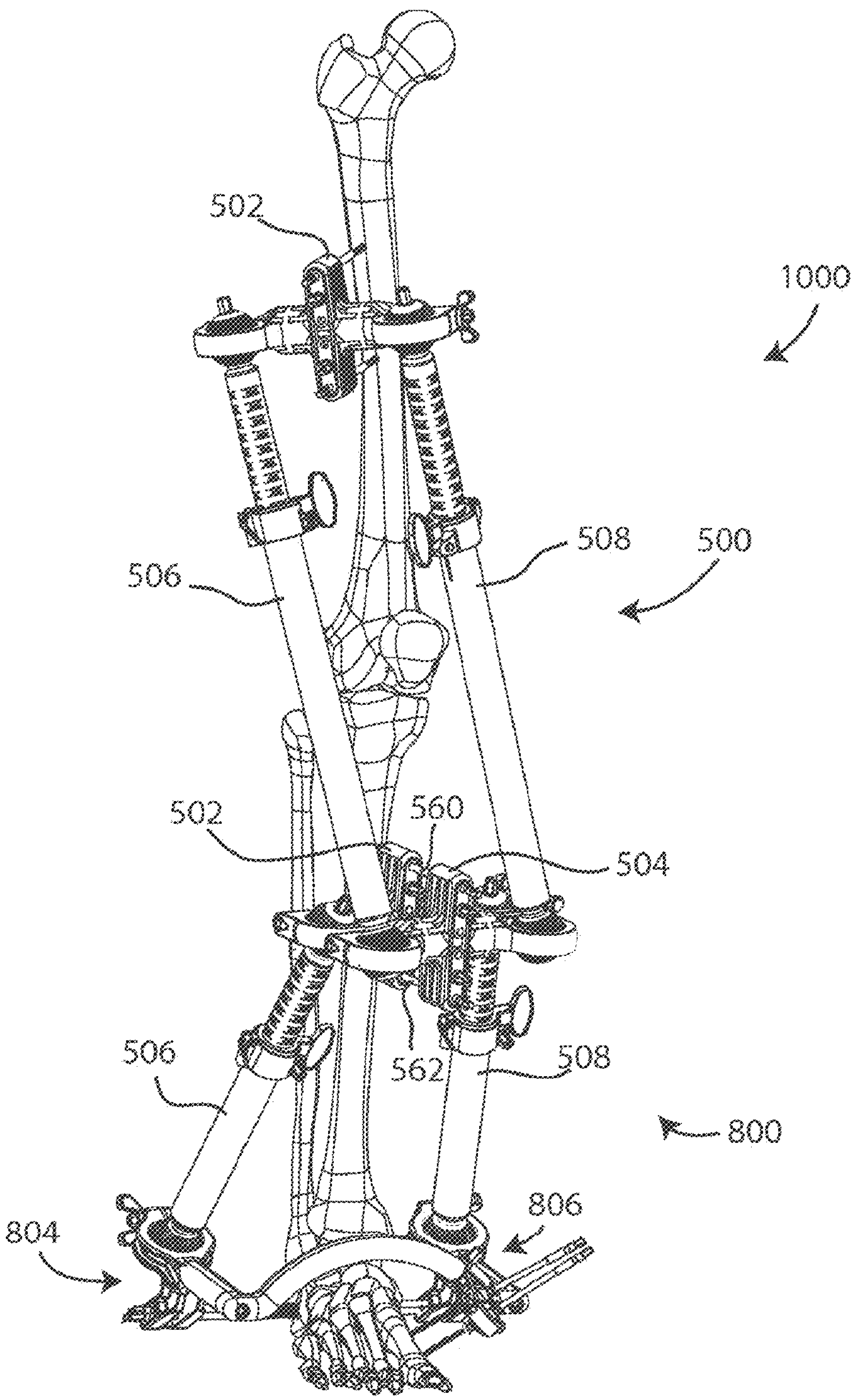


FIG. 19

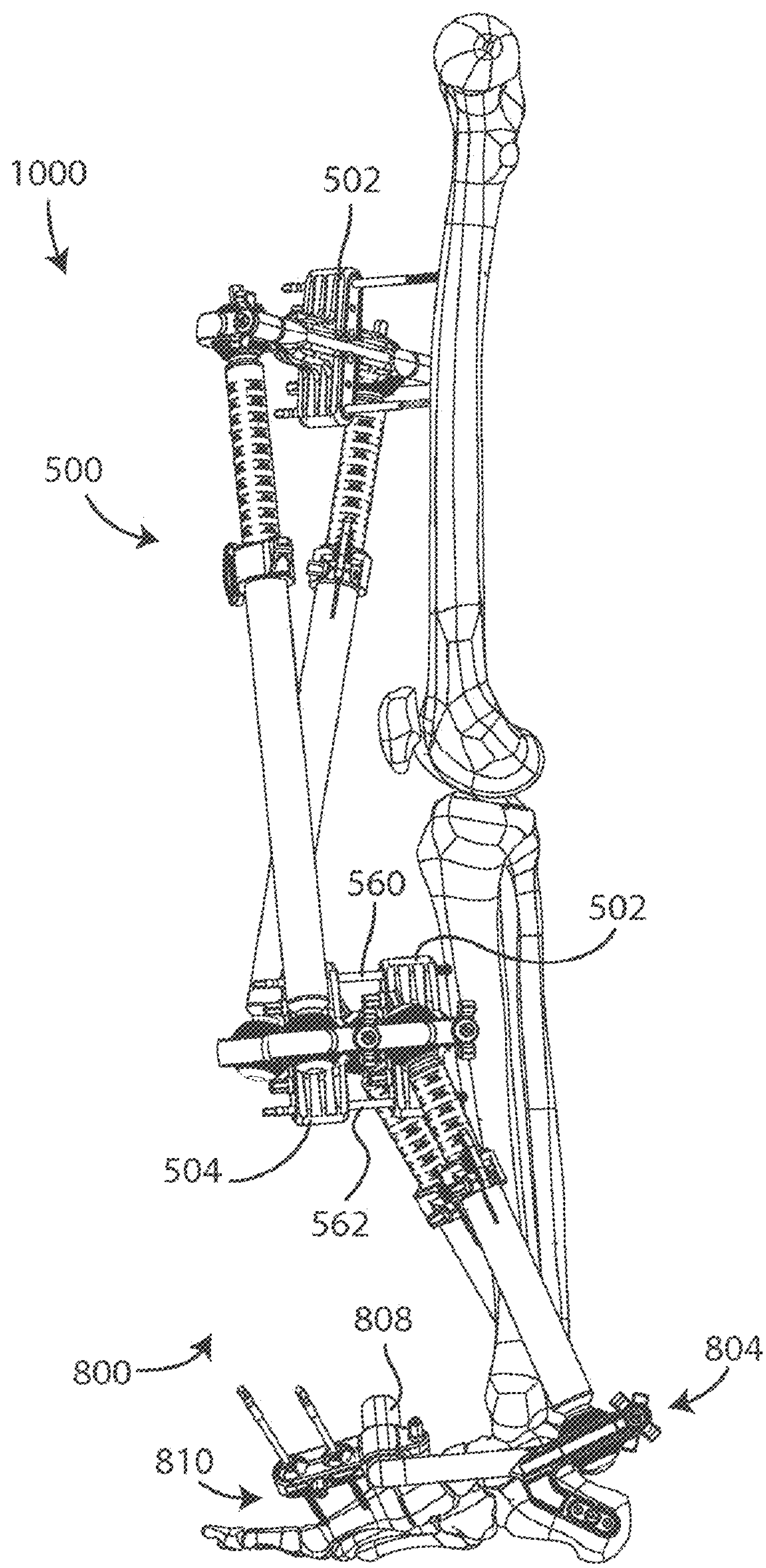


FIG. 20

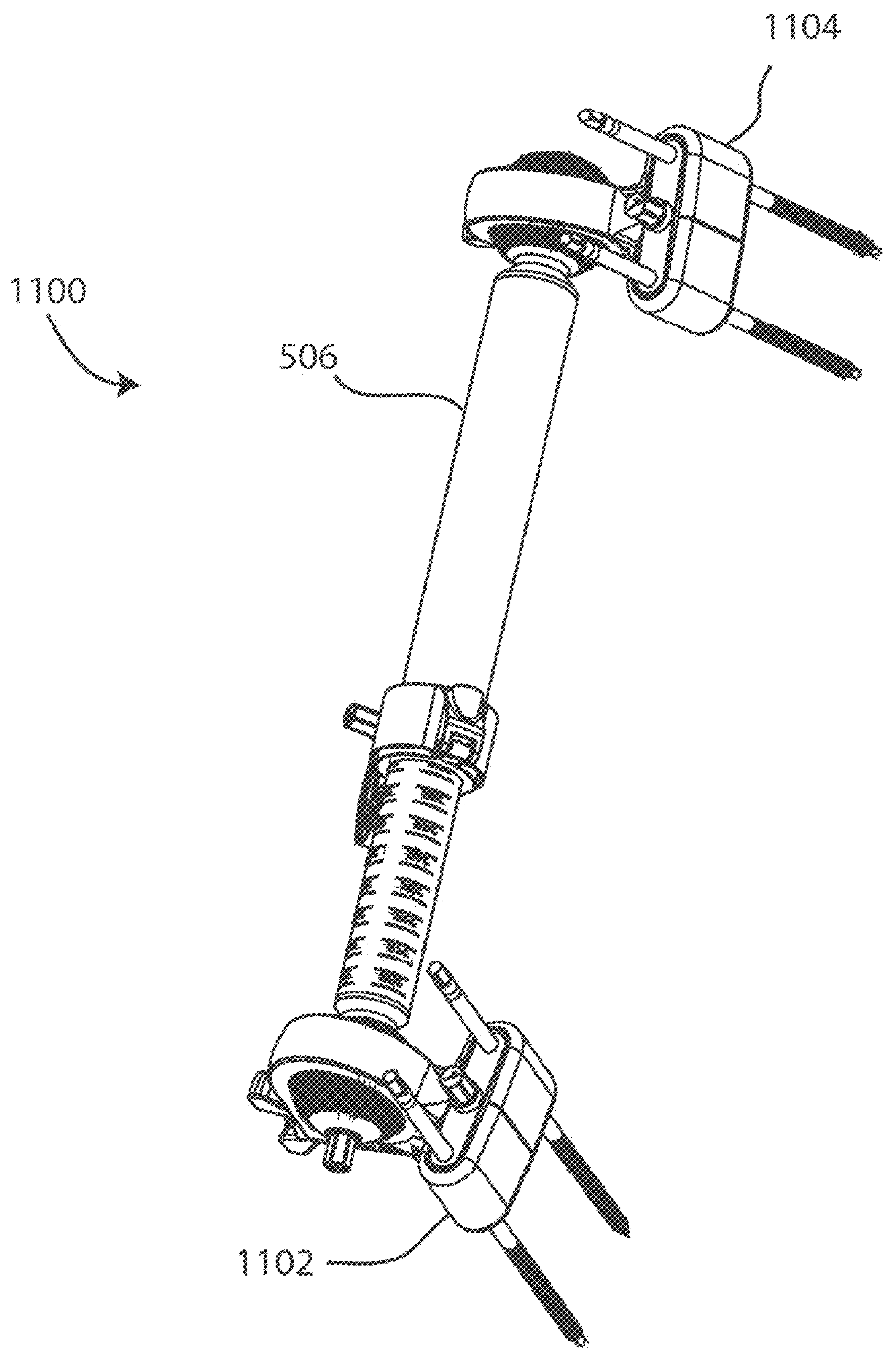


FIG. 21

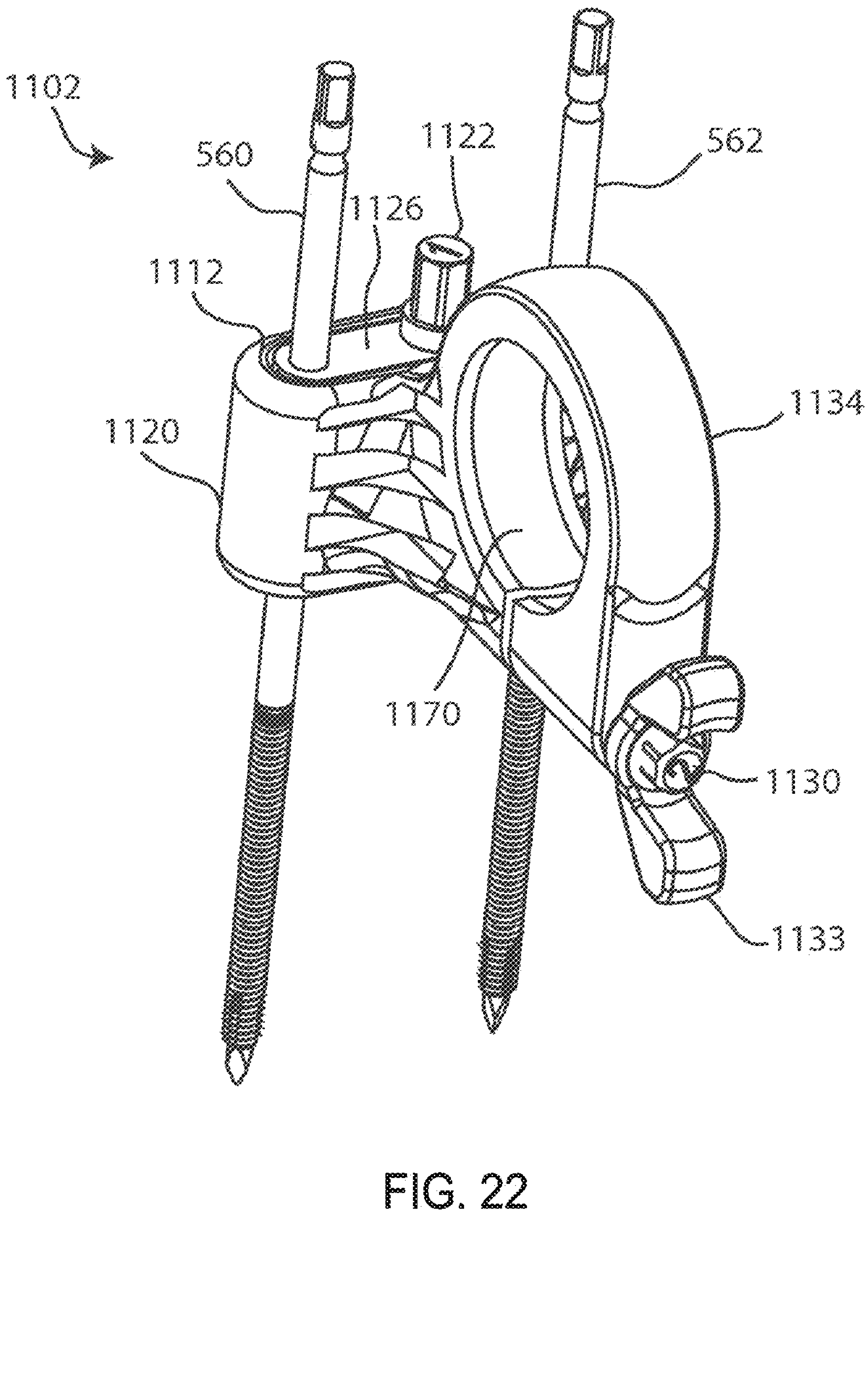
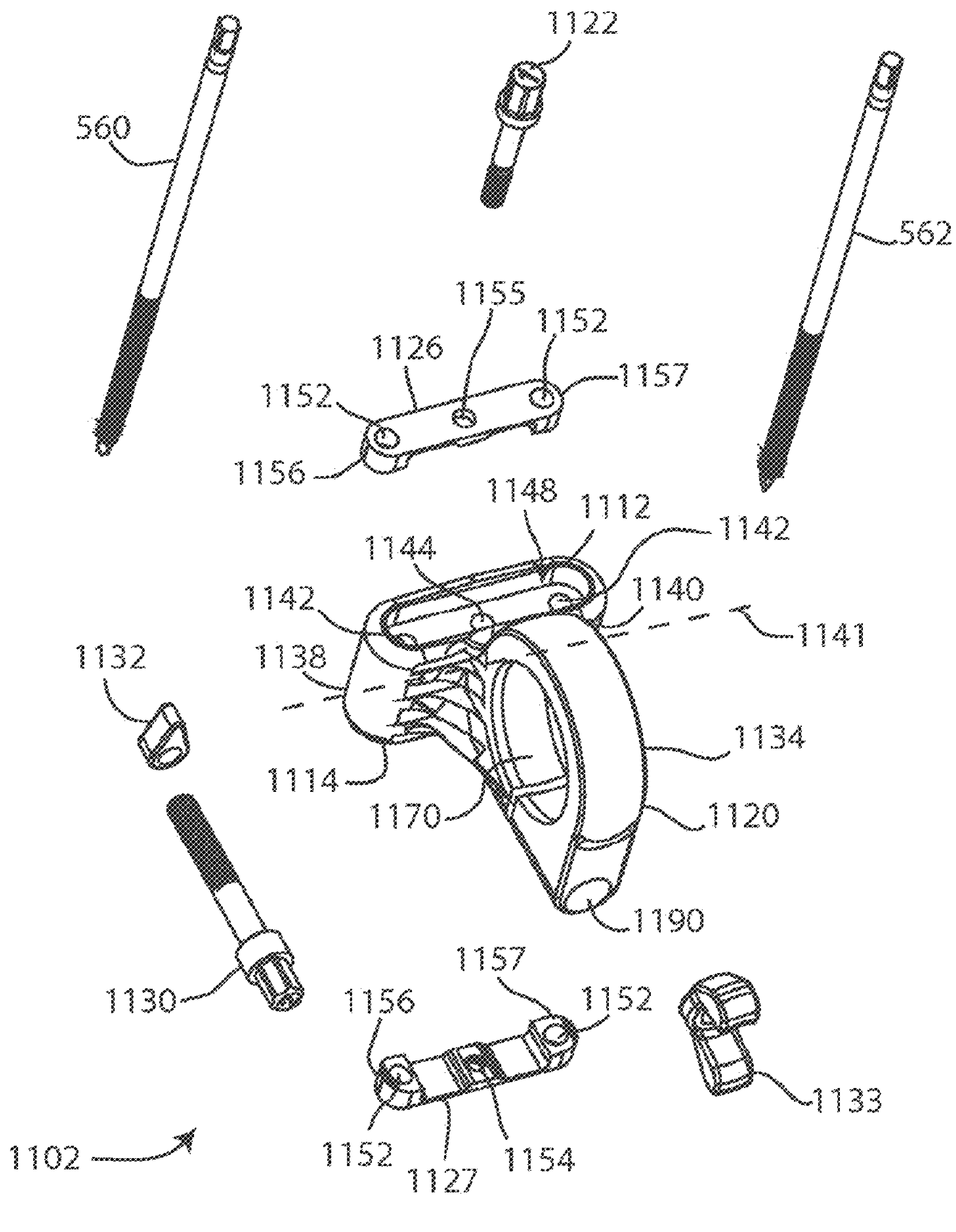


FIG. 22



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1102

FIG. 23

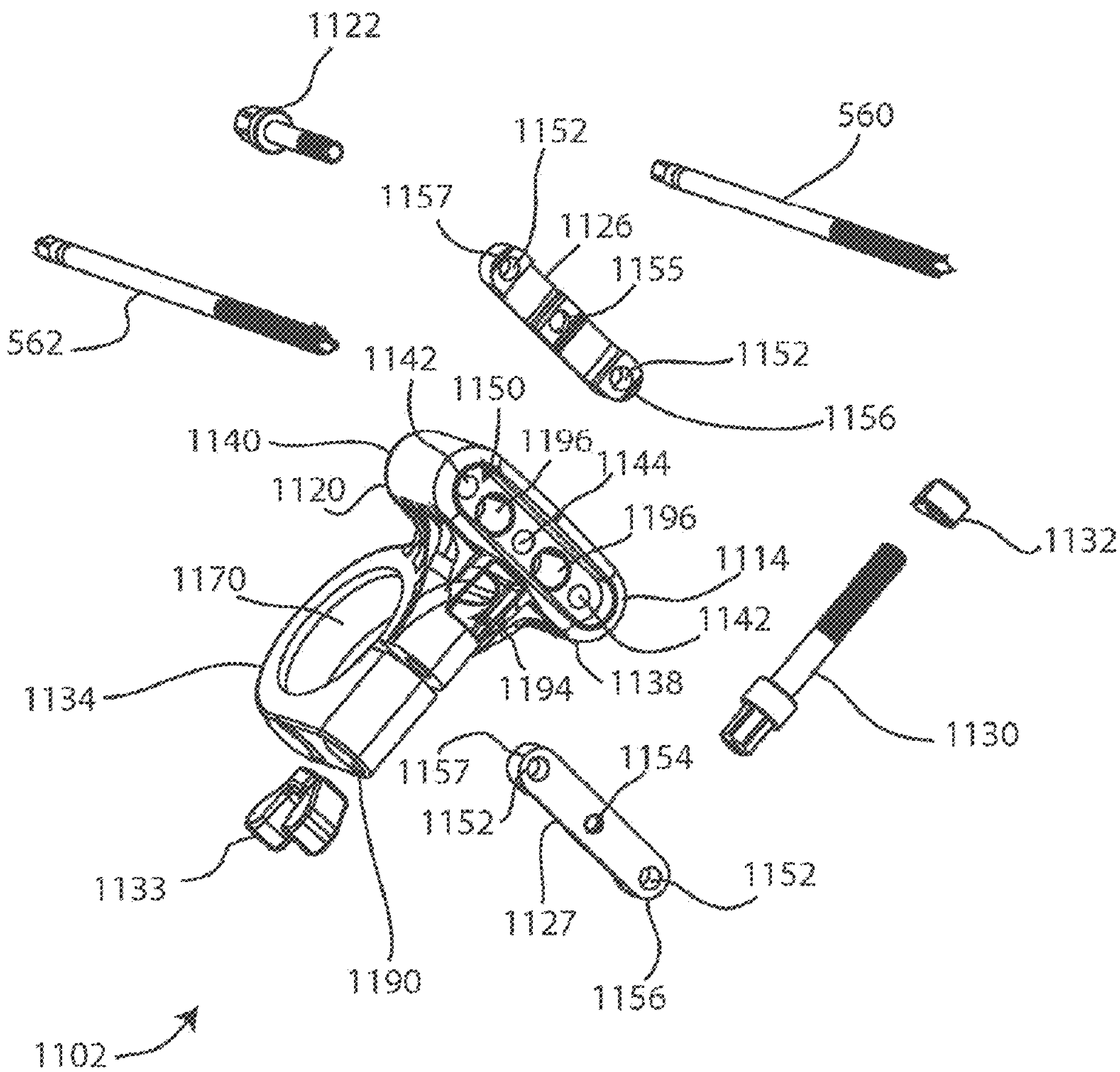
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FIG. 24

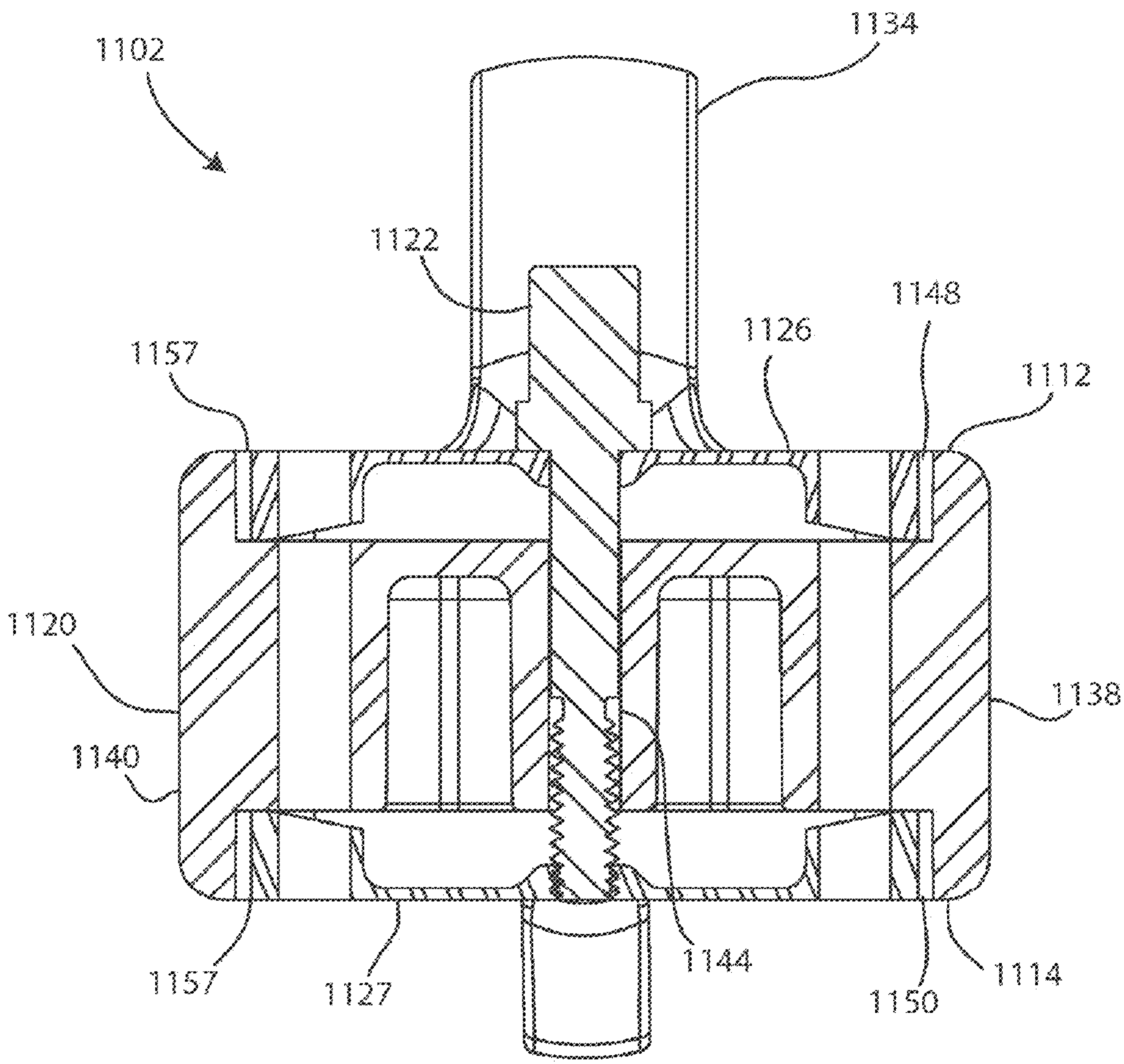
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FIG. 25

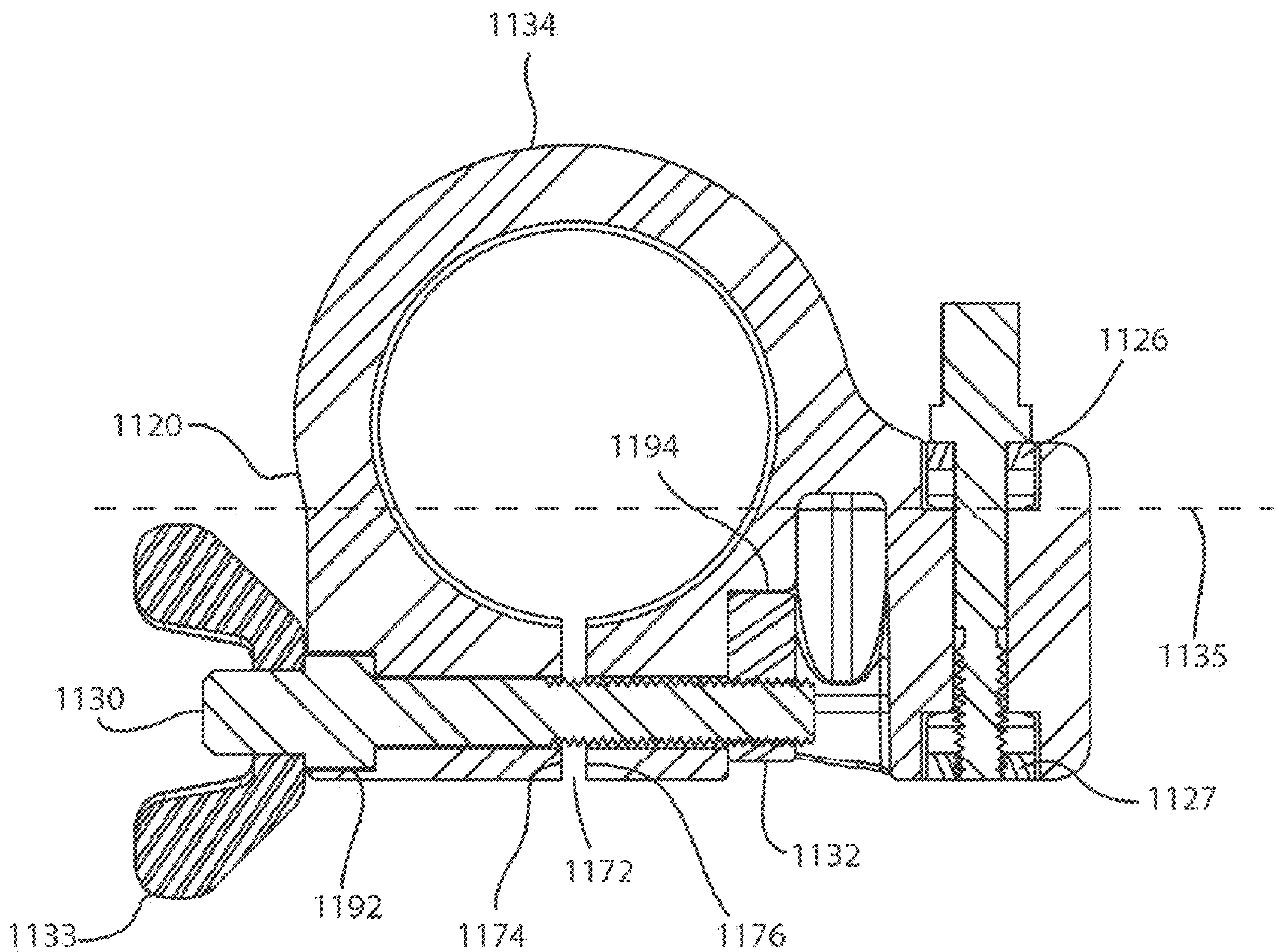
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FIG. 26

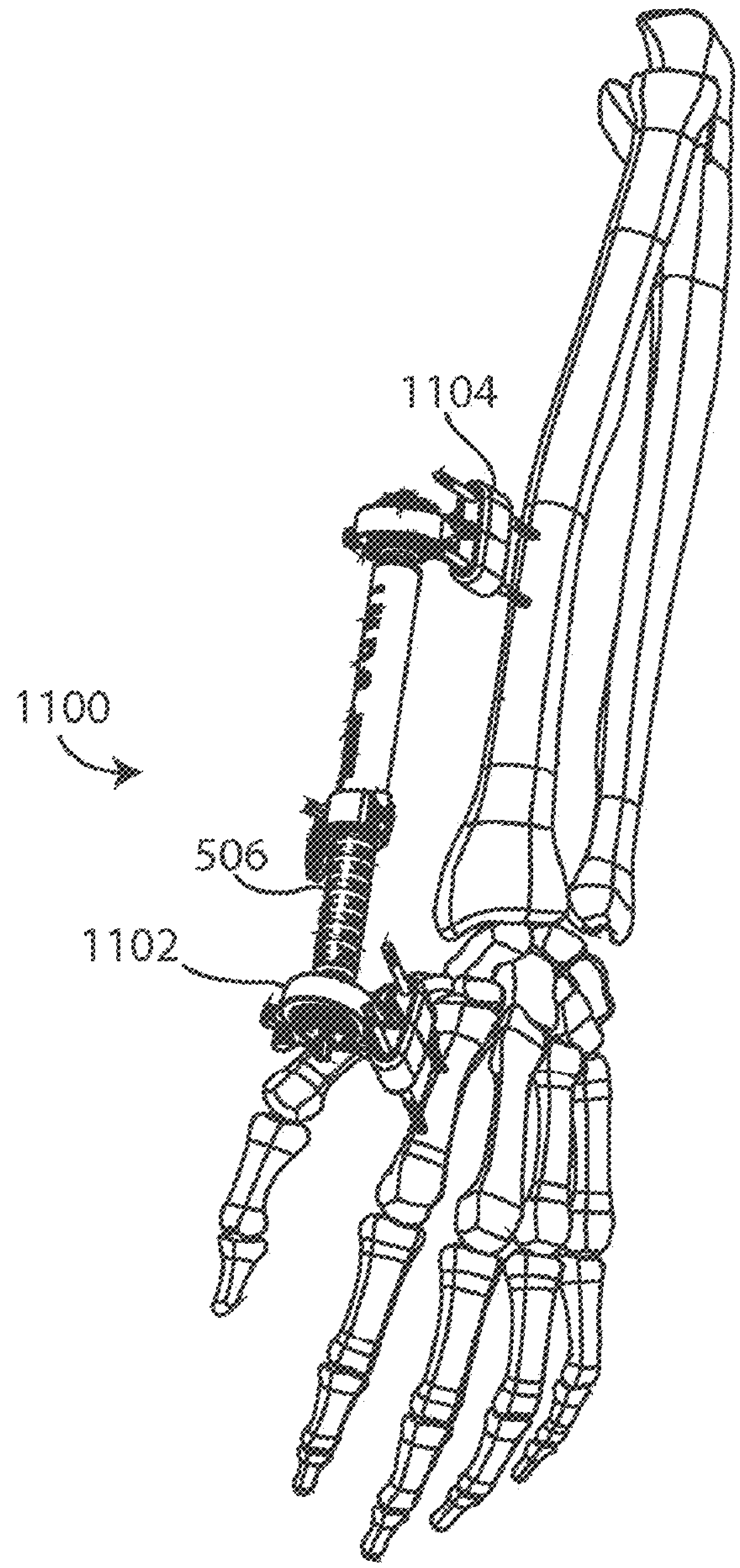


FIG. 27

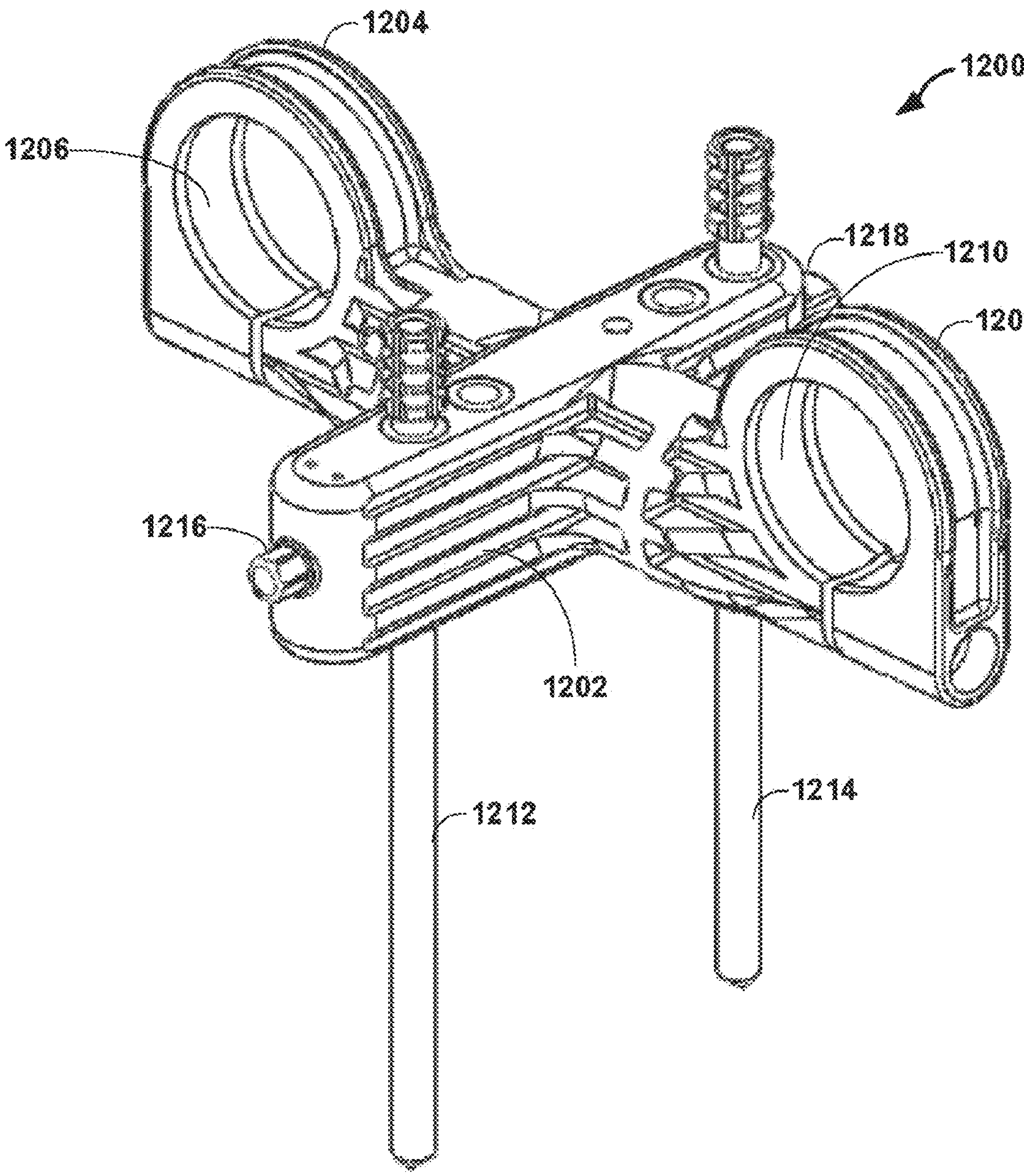
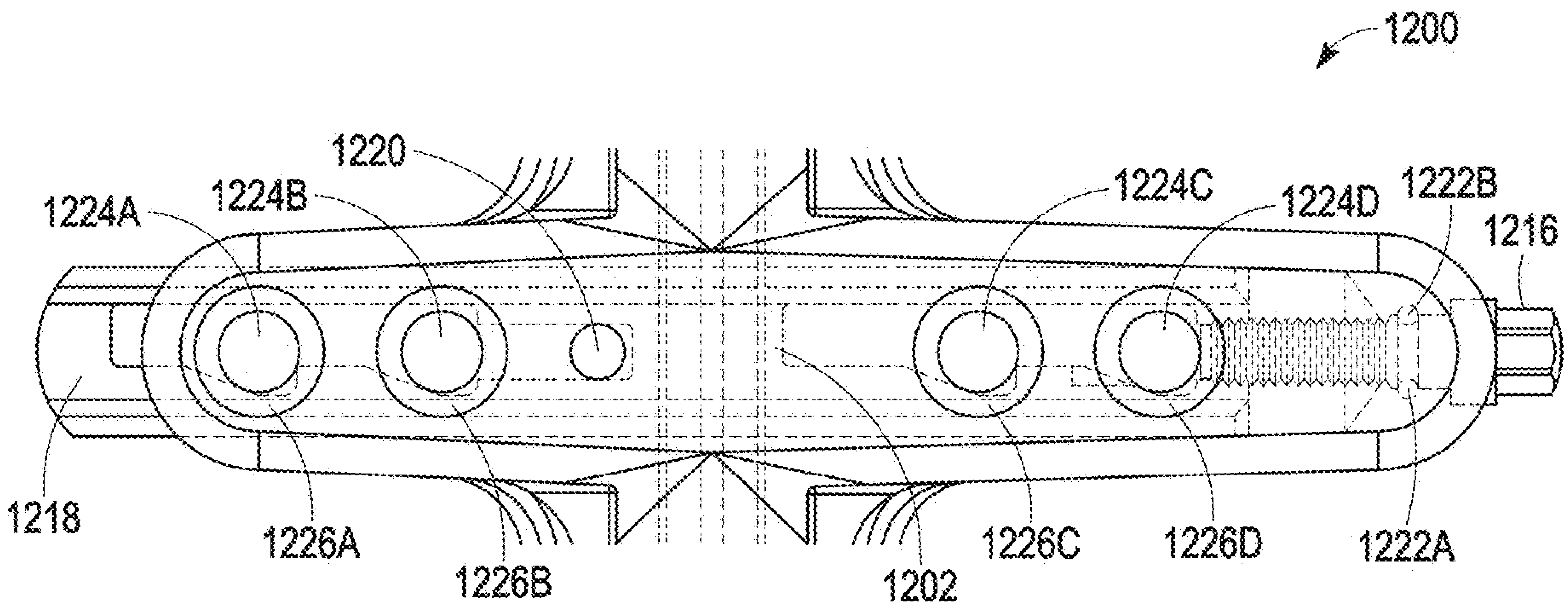


FIG. 28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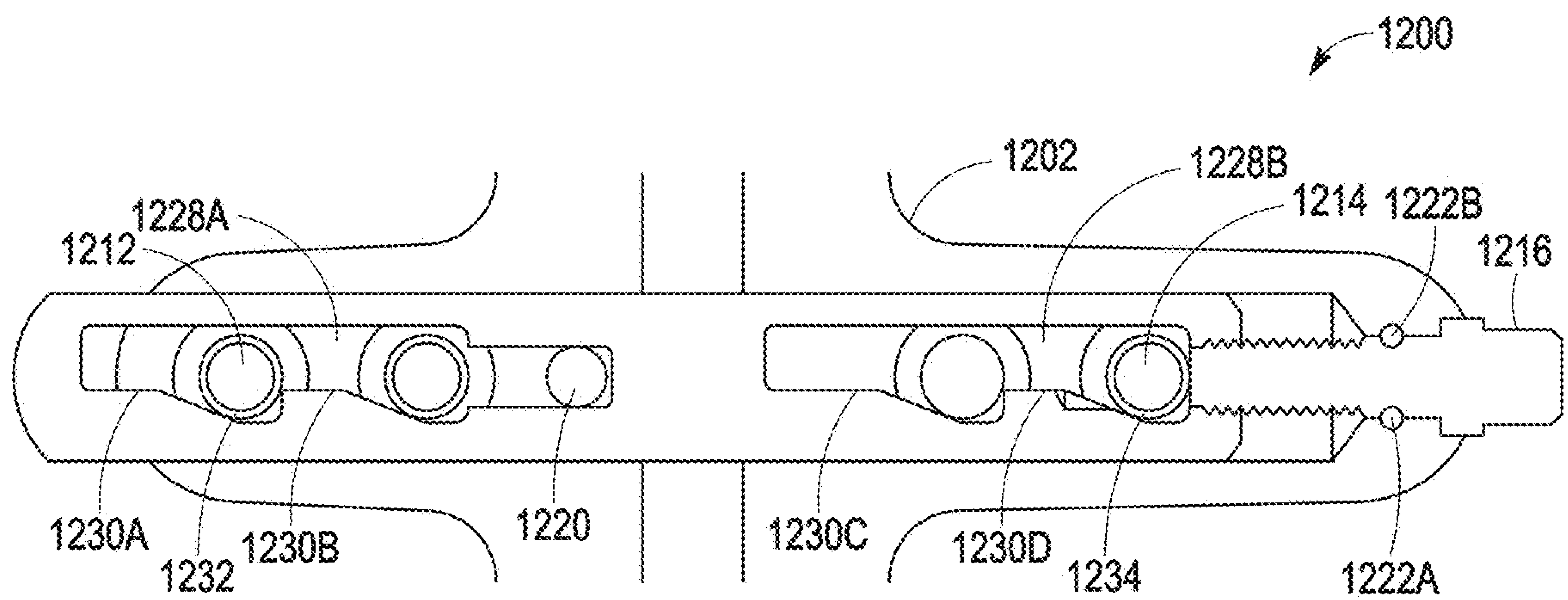
1220
1224A
1224B
1224C
1224D
1222B
1216
1218
1226A
1226B
1202
1226C
1226D
1222A

FIG. 29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1228B
1214
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1228A
1212
1216
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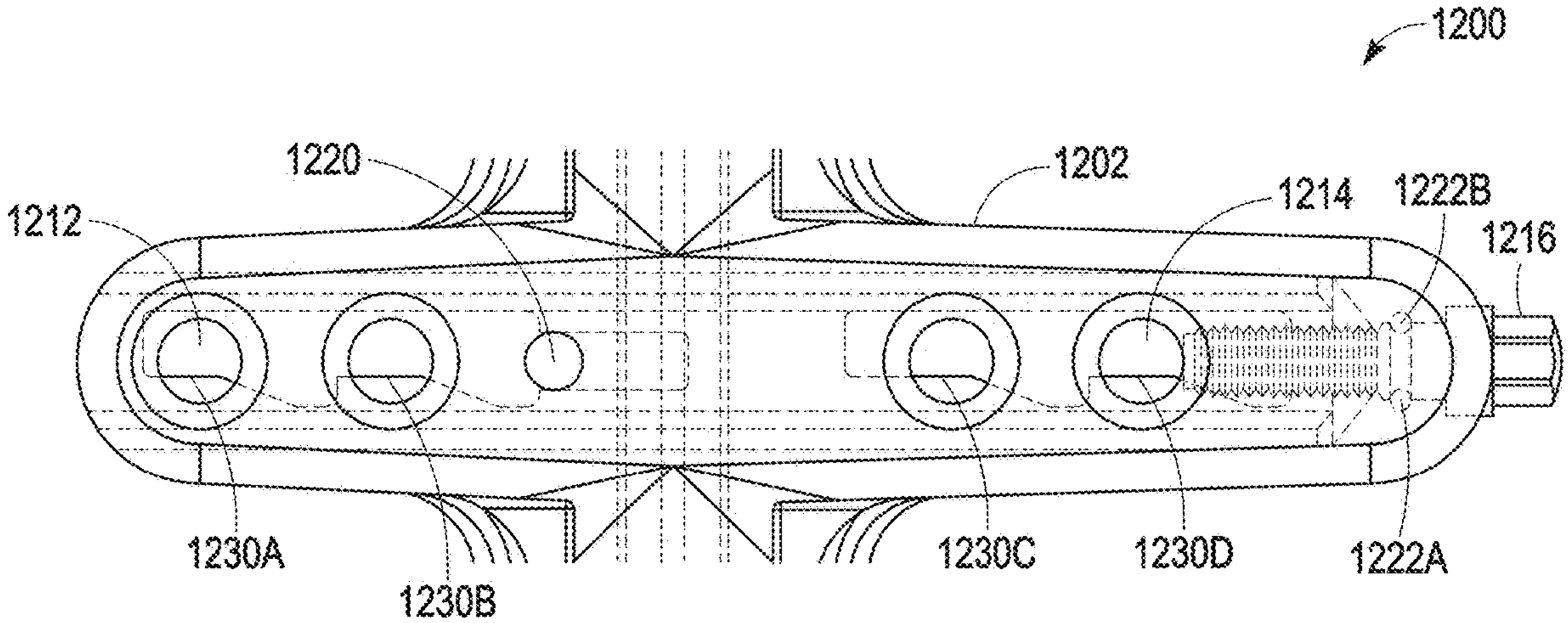
1232
1230B
1220
1230C
1230D
1234
1222A

FIG. 30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1216
1230A
1230B
1230C
1230D
1222A

FIG. 31

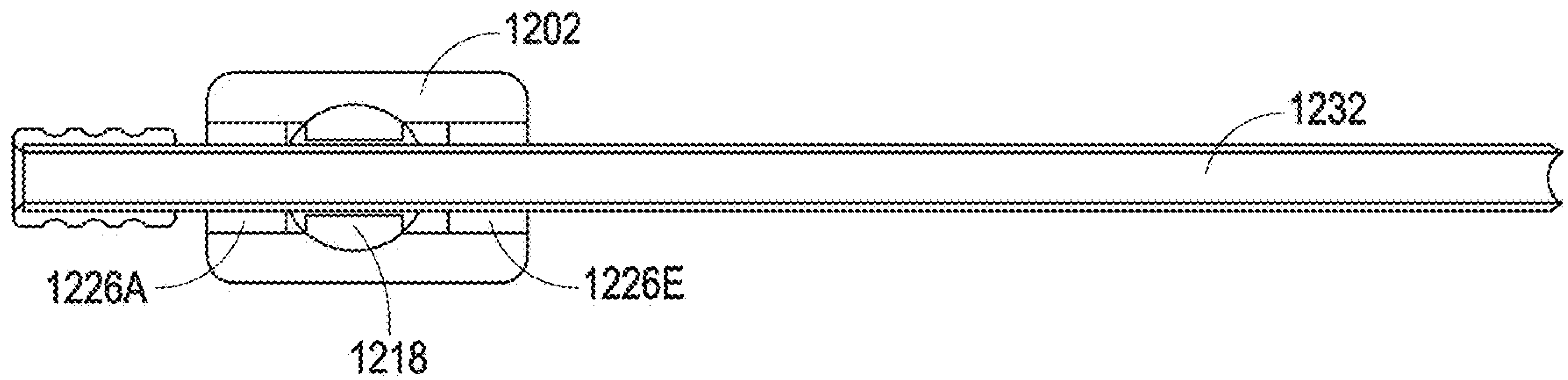

1202
1232
1226A
1226E
1218

FIG. 32

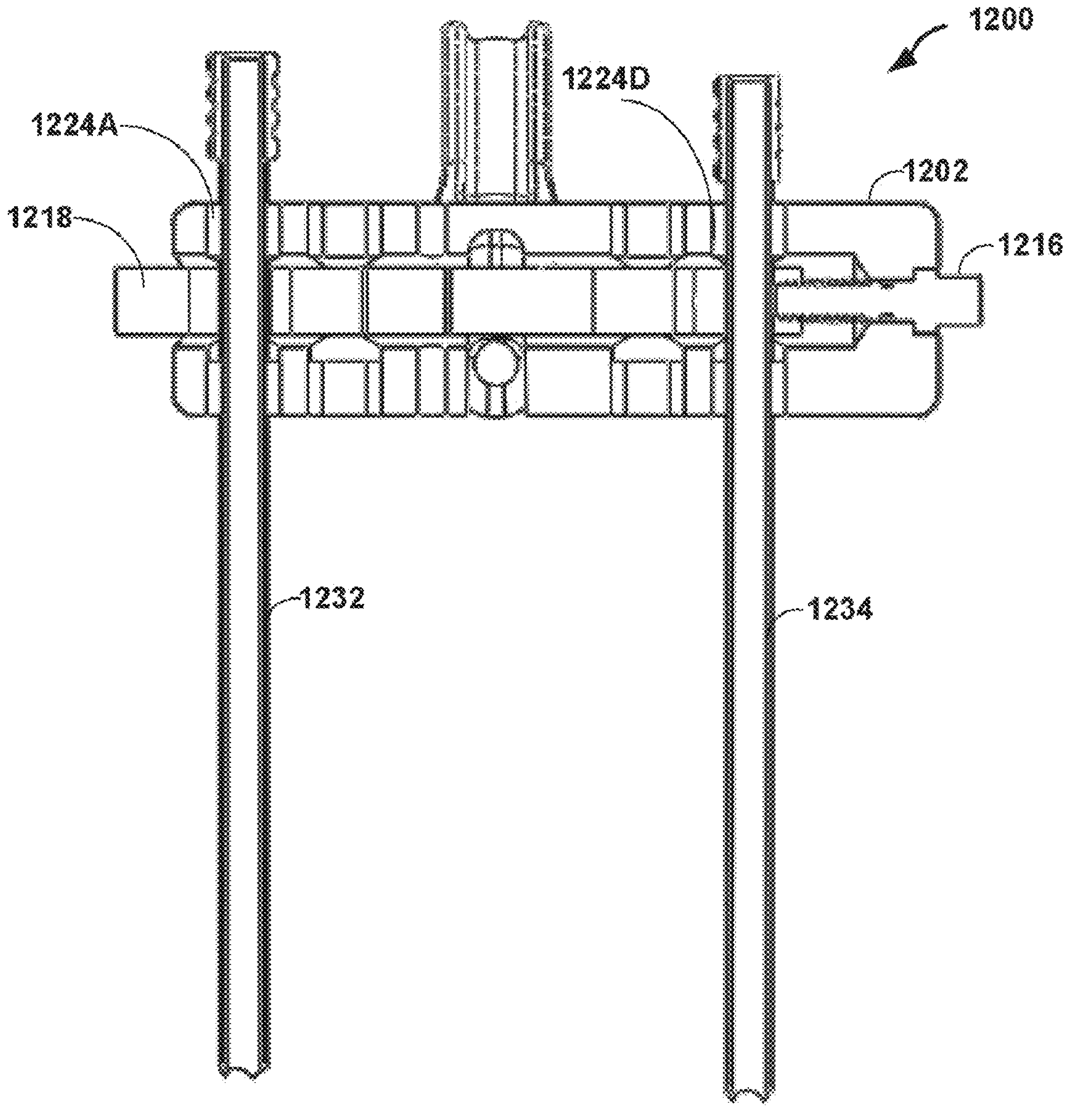


FIG. 33

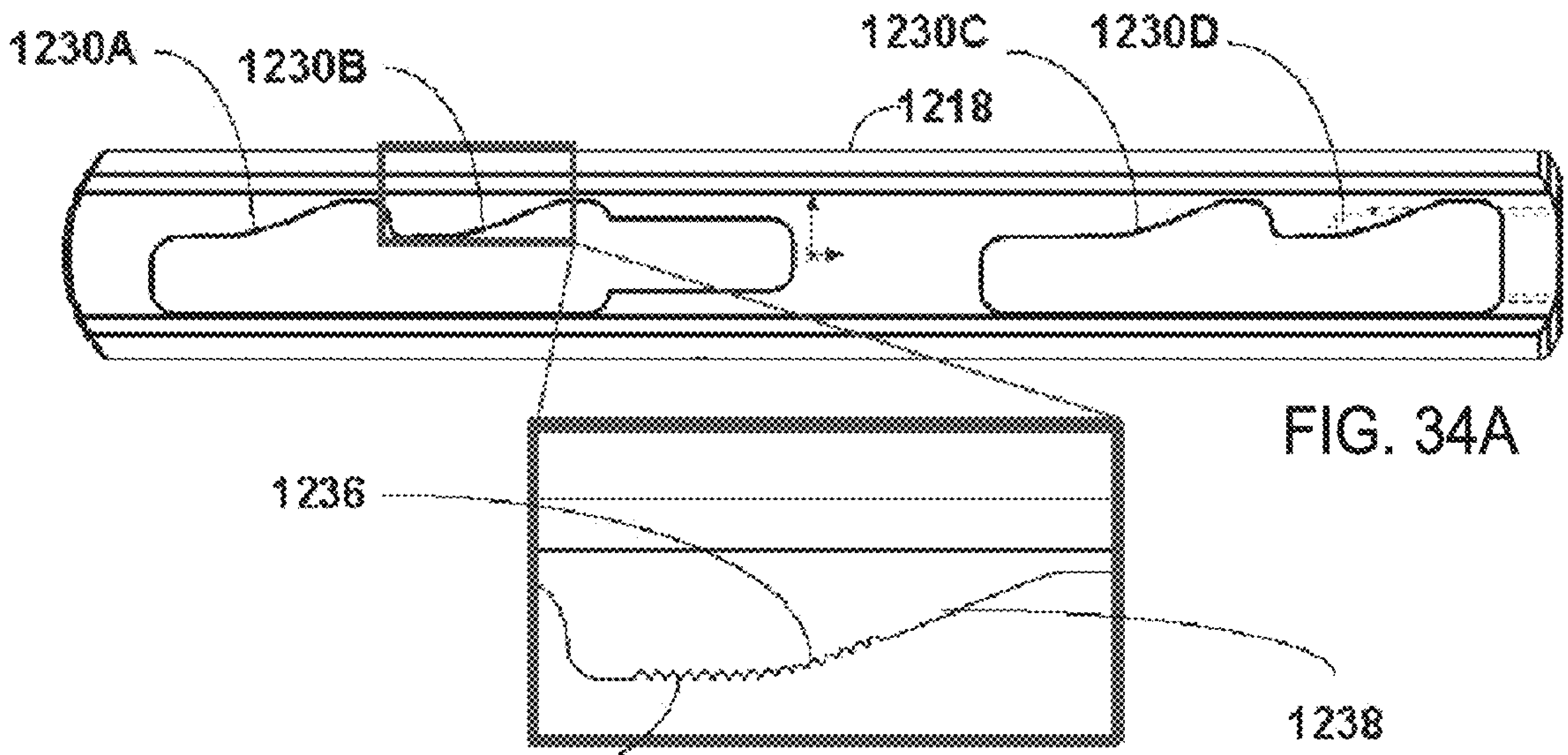


FIG. 34A

FIG. 34B

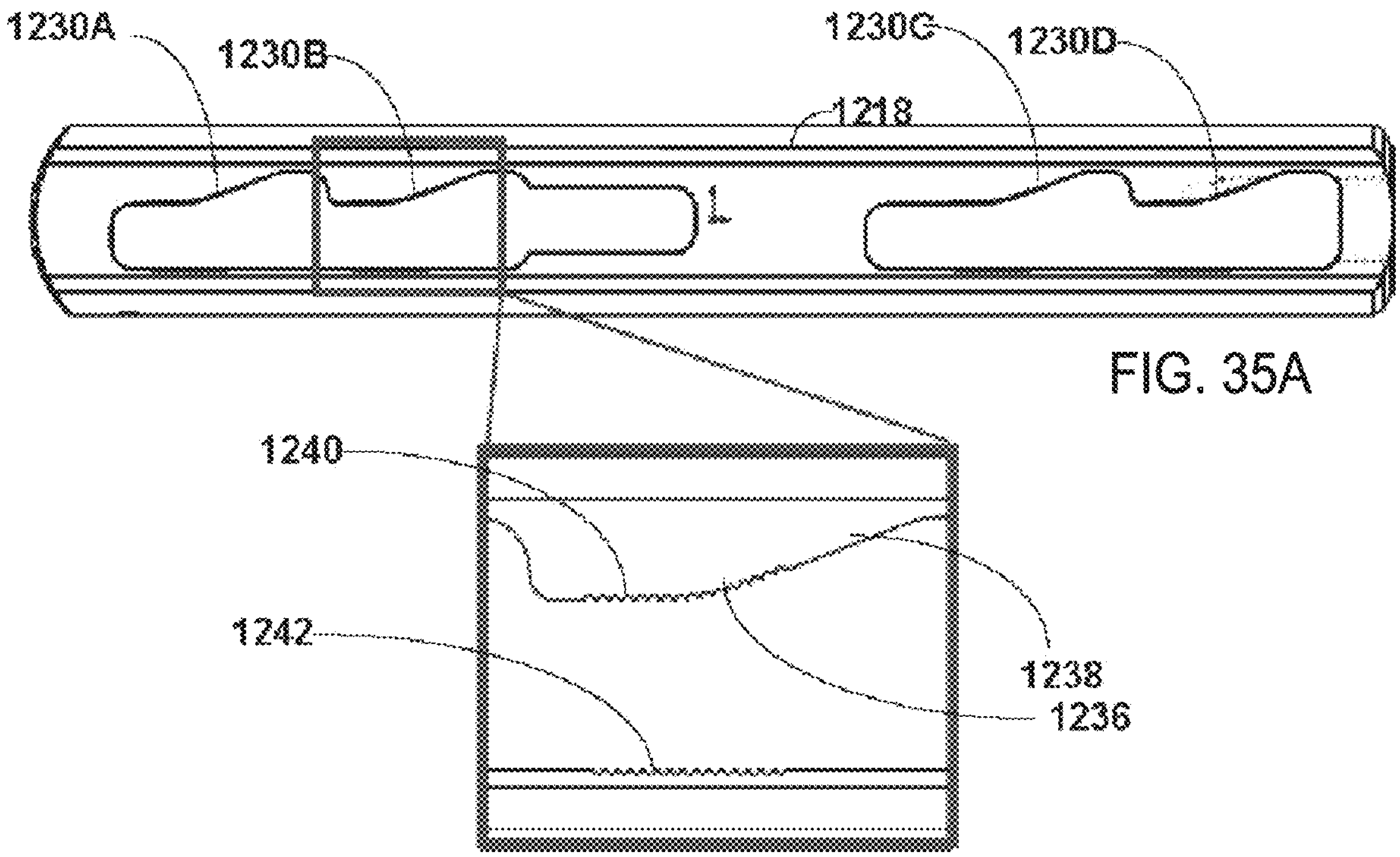
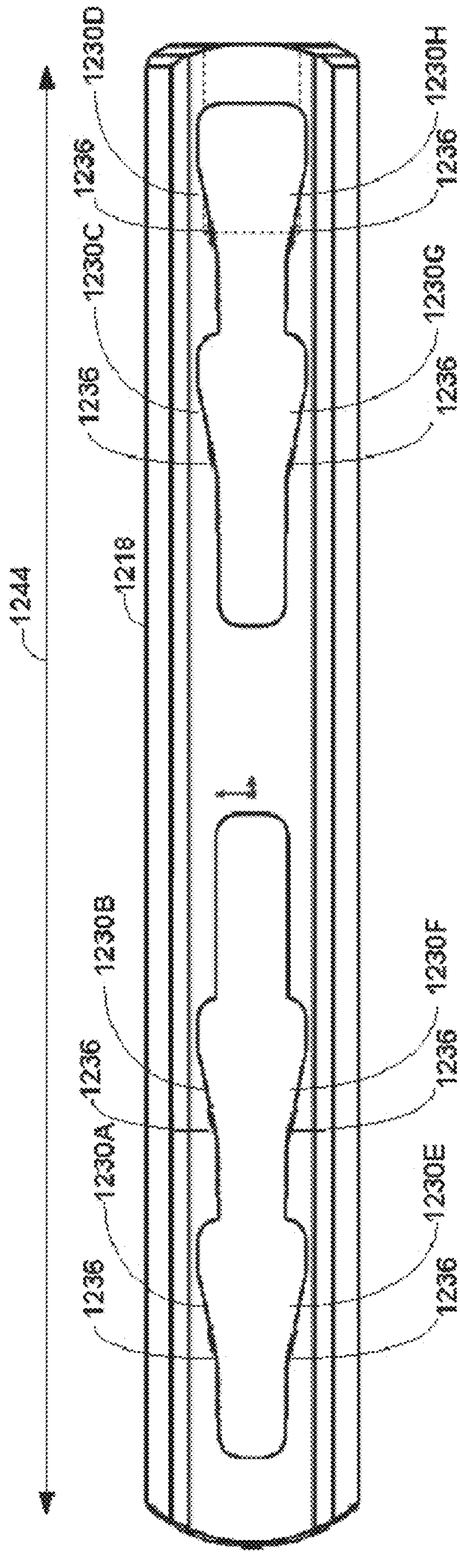


FIG. 35A

FIG. 35B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1230C
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1244
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1230A
1230E
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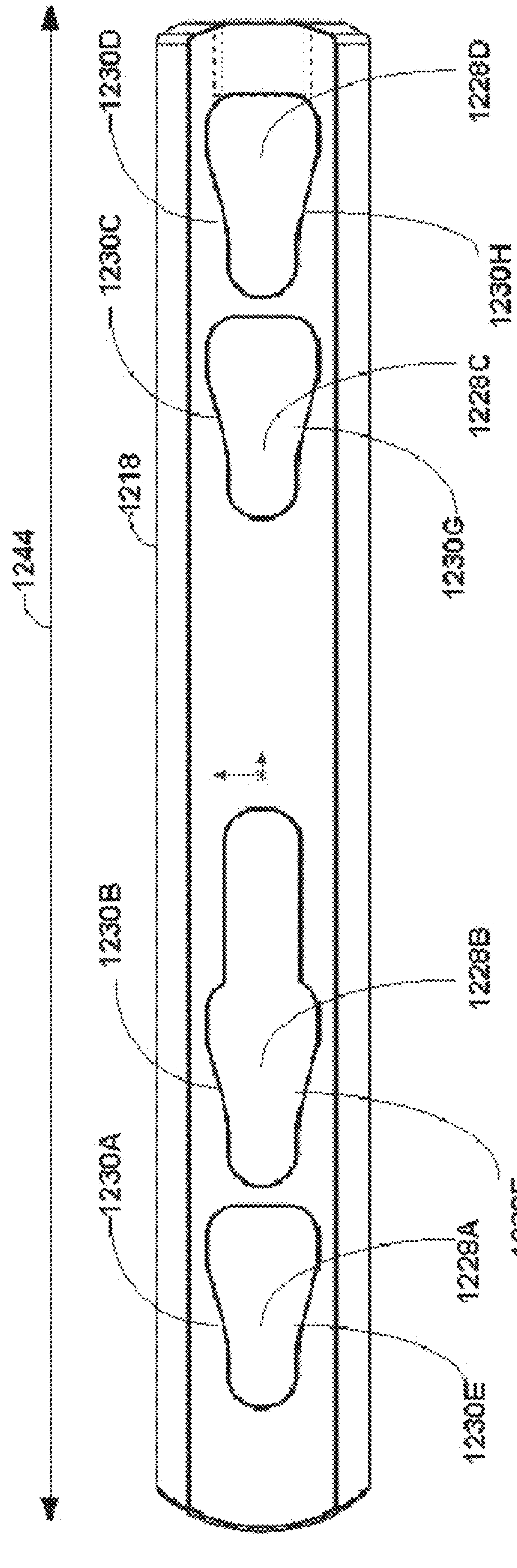
1236

FIG. 36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1218
1244
L
1230B
1228B
1230F
1230A
1228A
1230E

FIG. 37

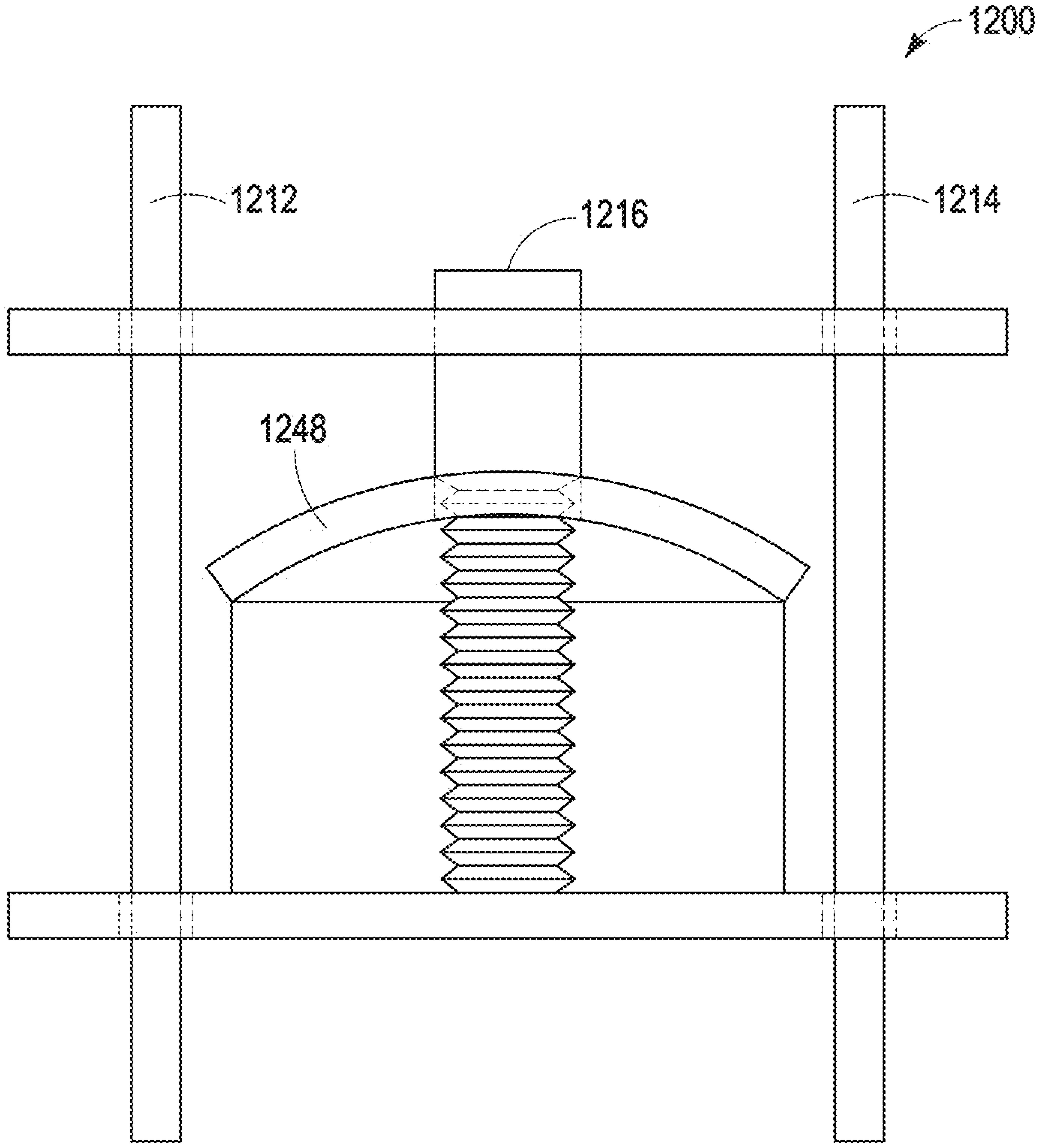


FIG. 38

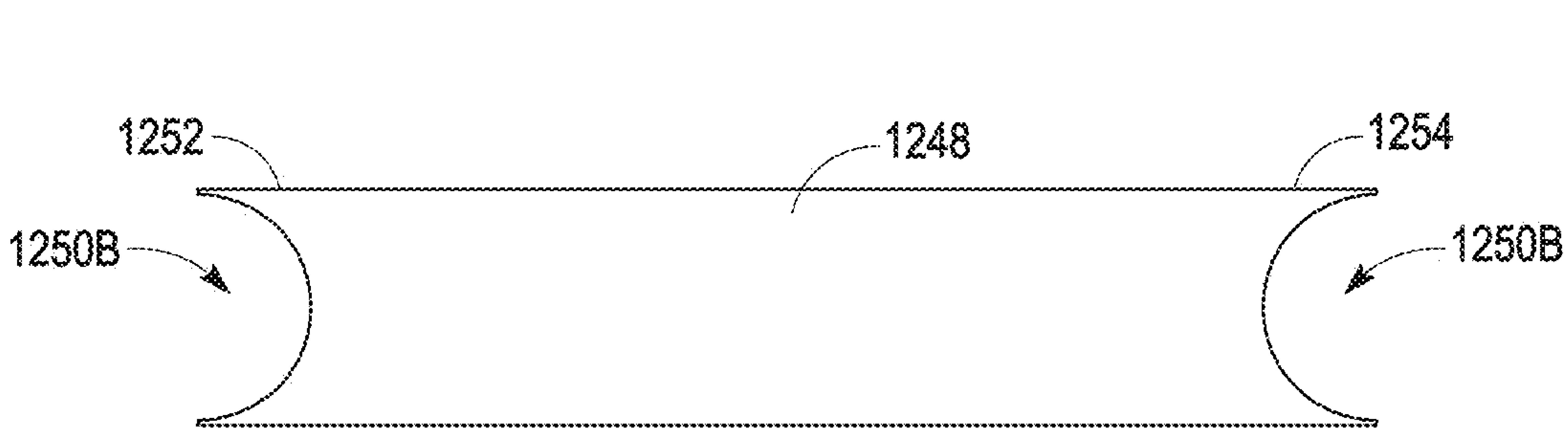
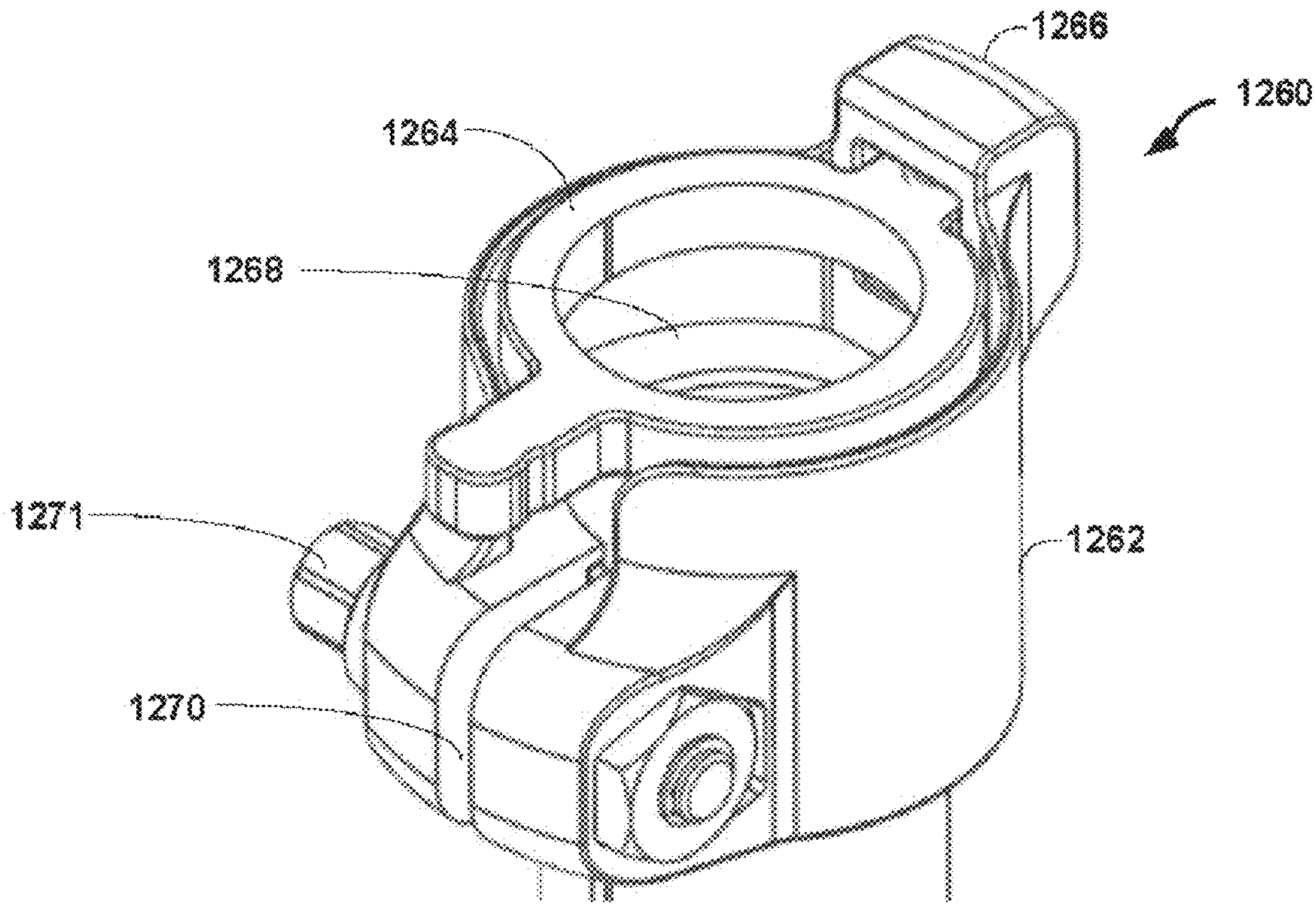


FIG. 39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1270

FIG. 40

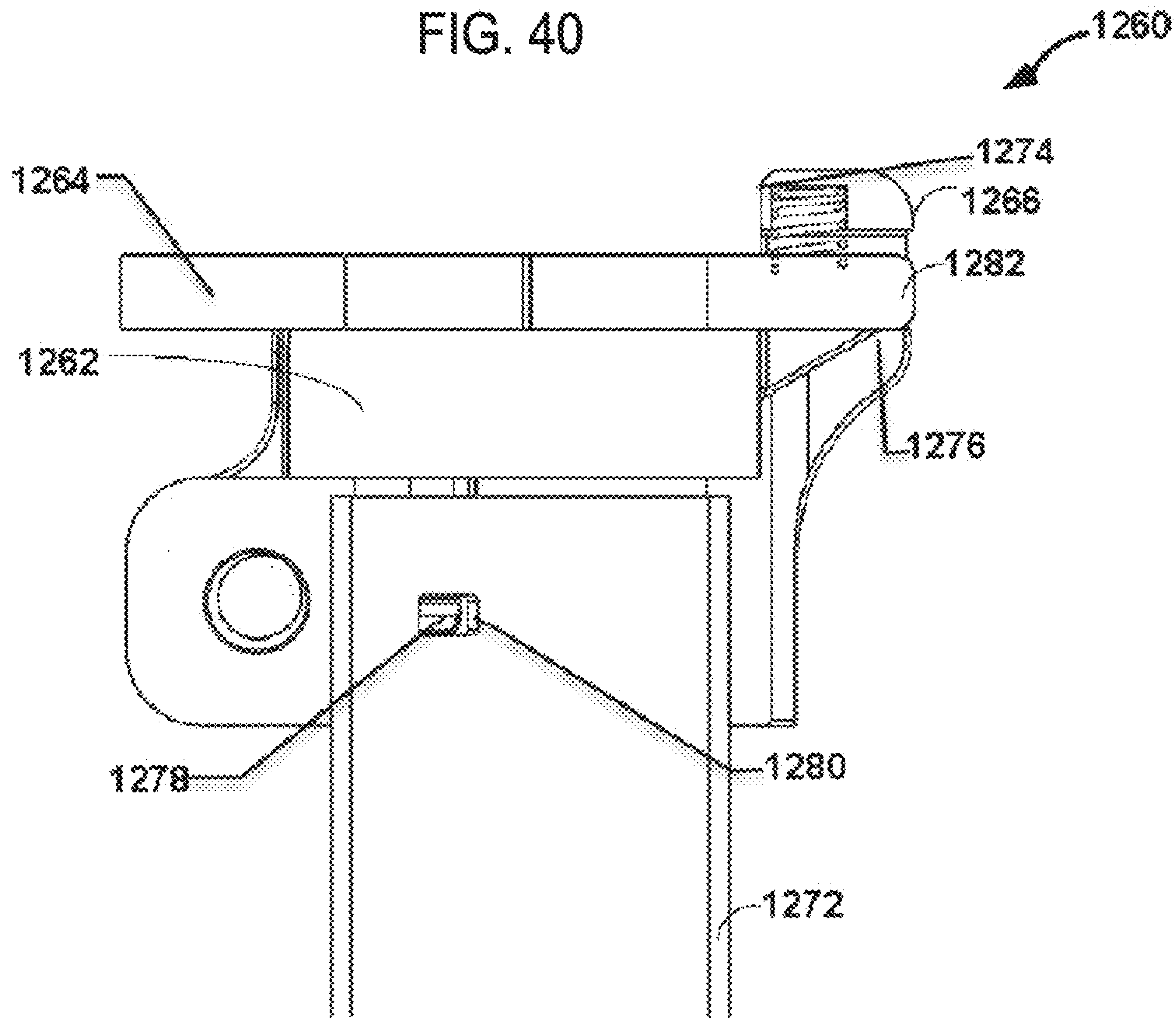
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FIG. 41

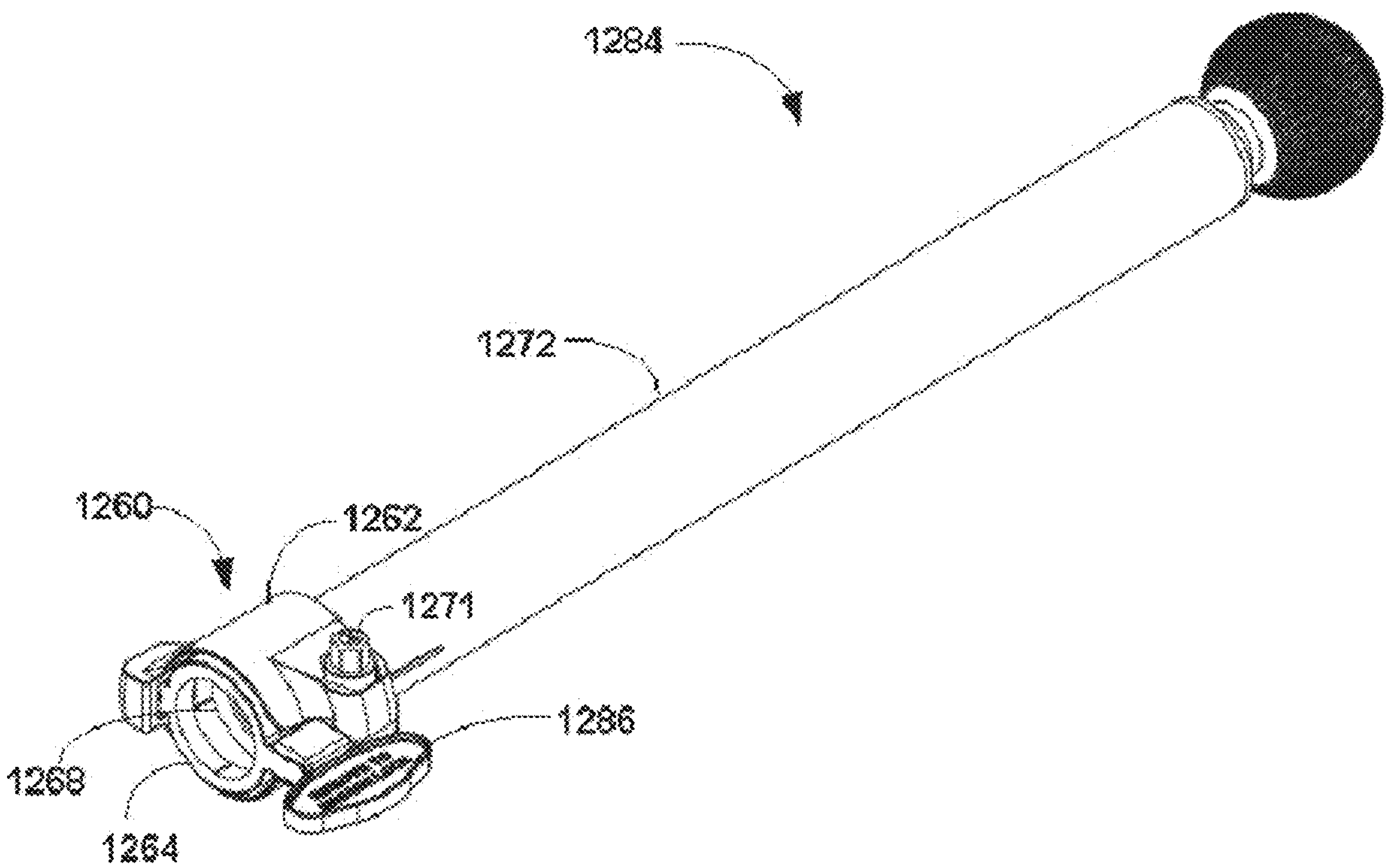


FIG. 42

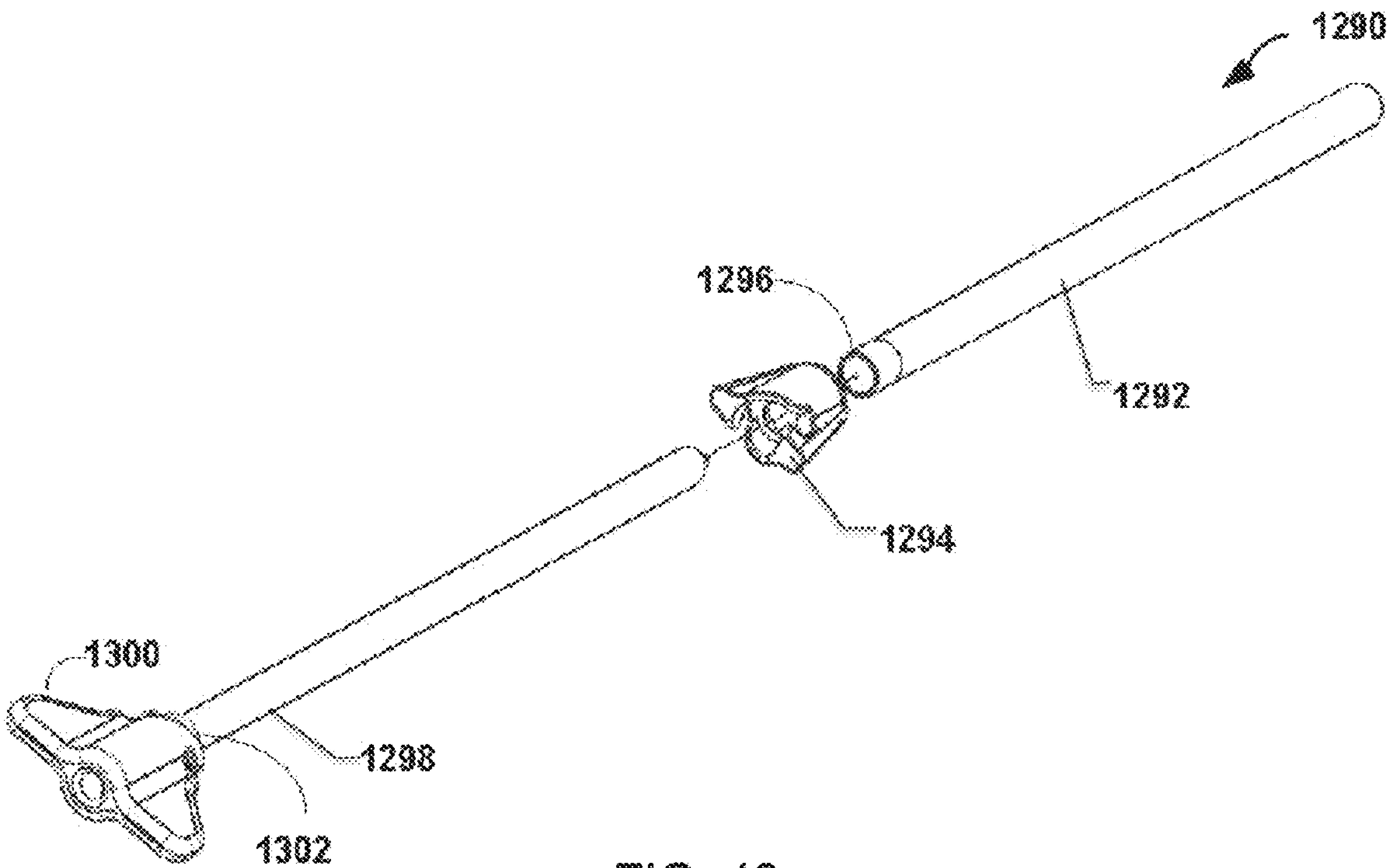


FIG. 43

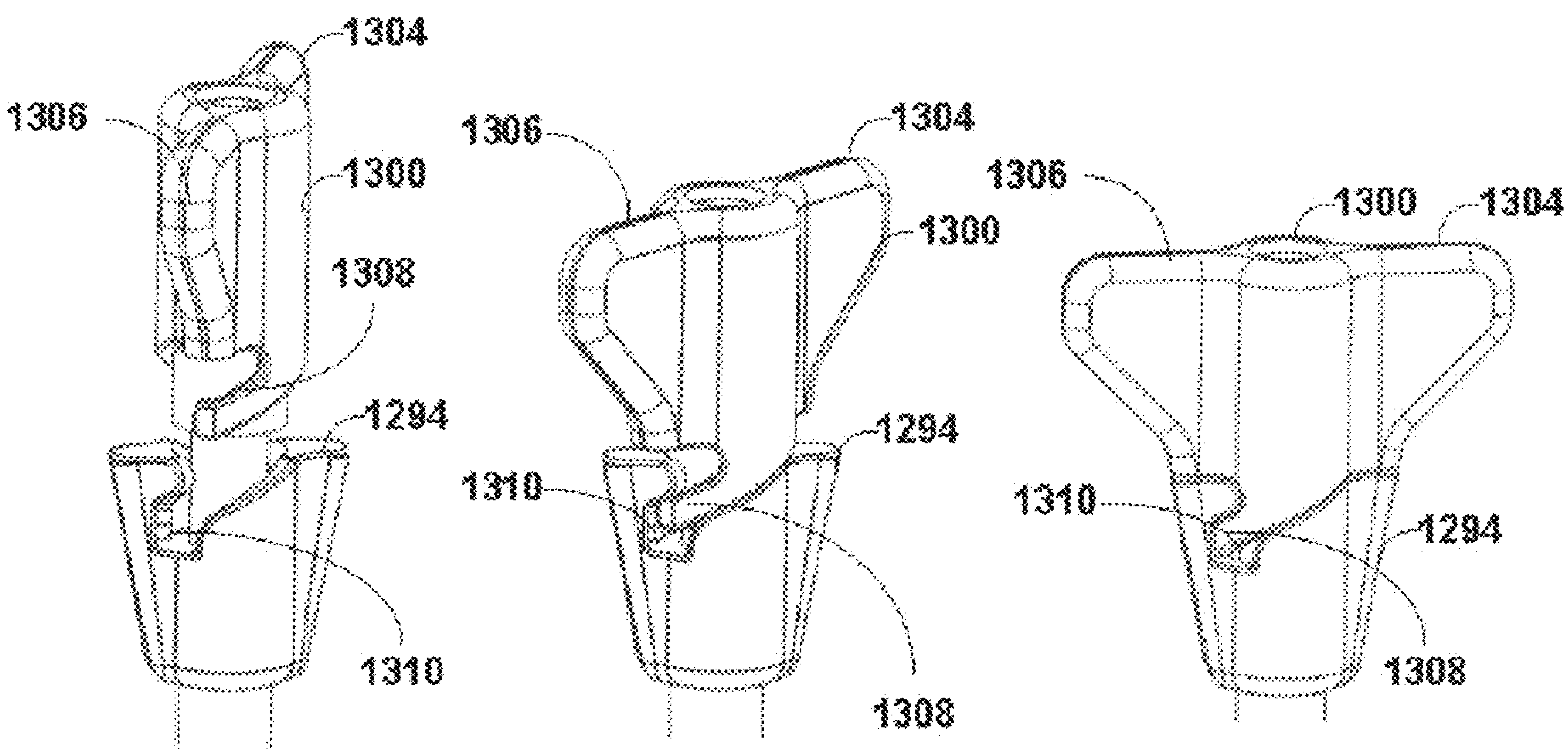


FIG. 44A FIG. 44B FIG. 44C

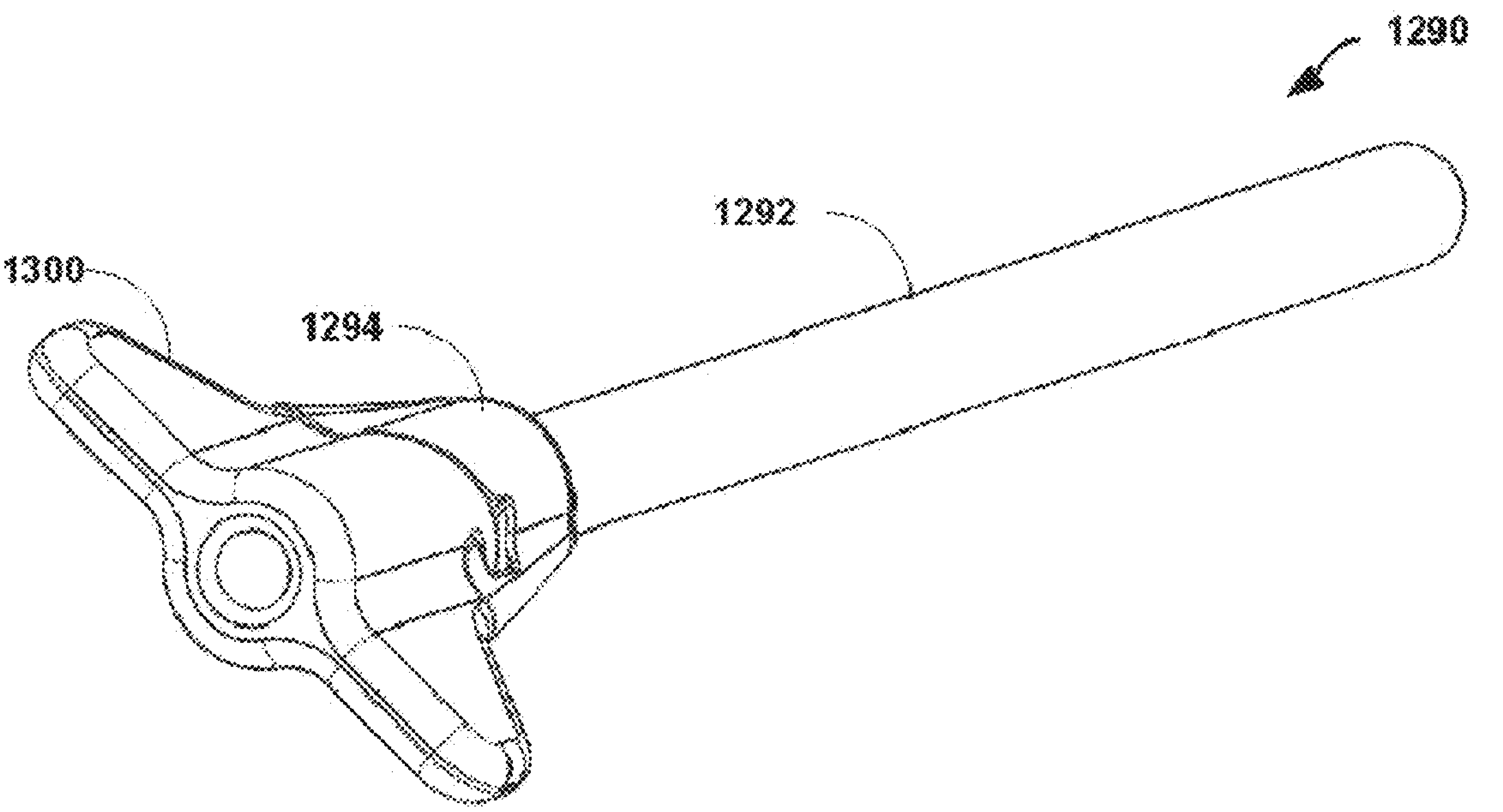


FIG. 45

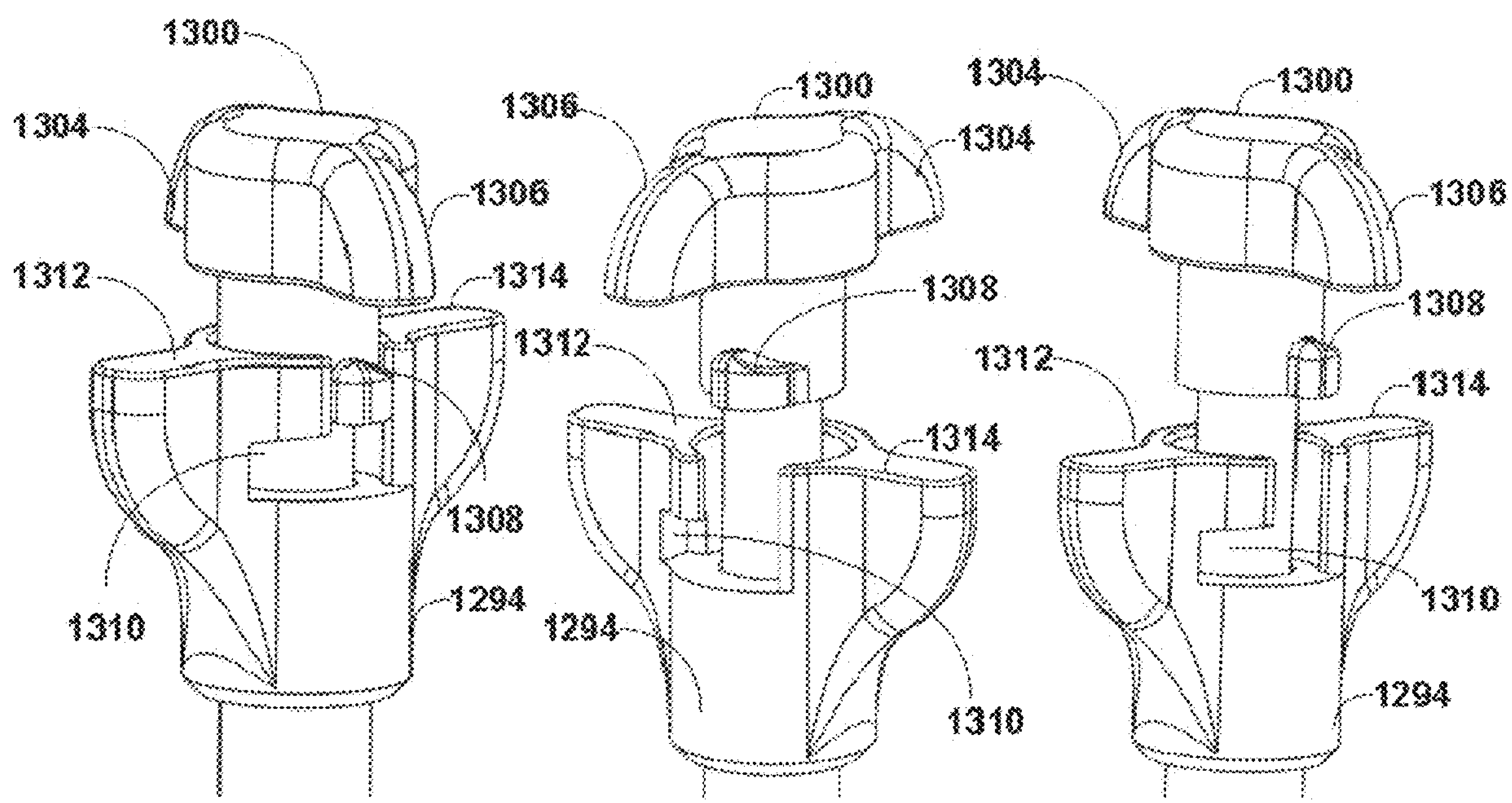


FIG. 46A FIG. 46B FIG. 46C

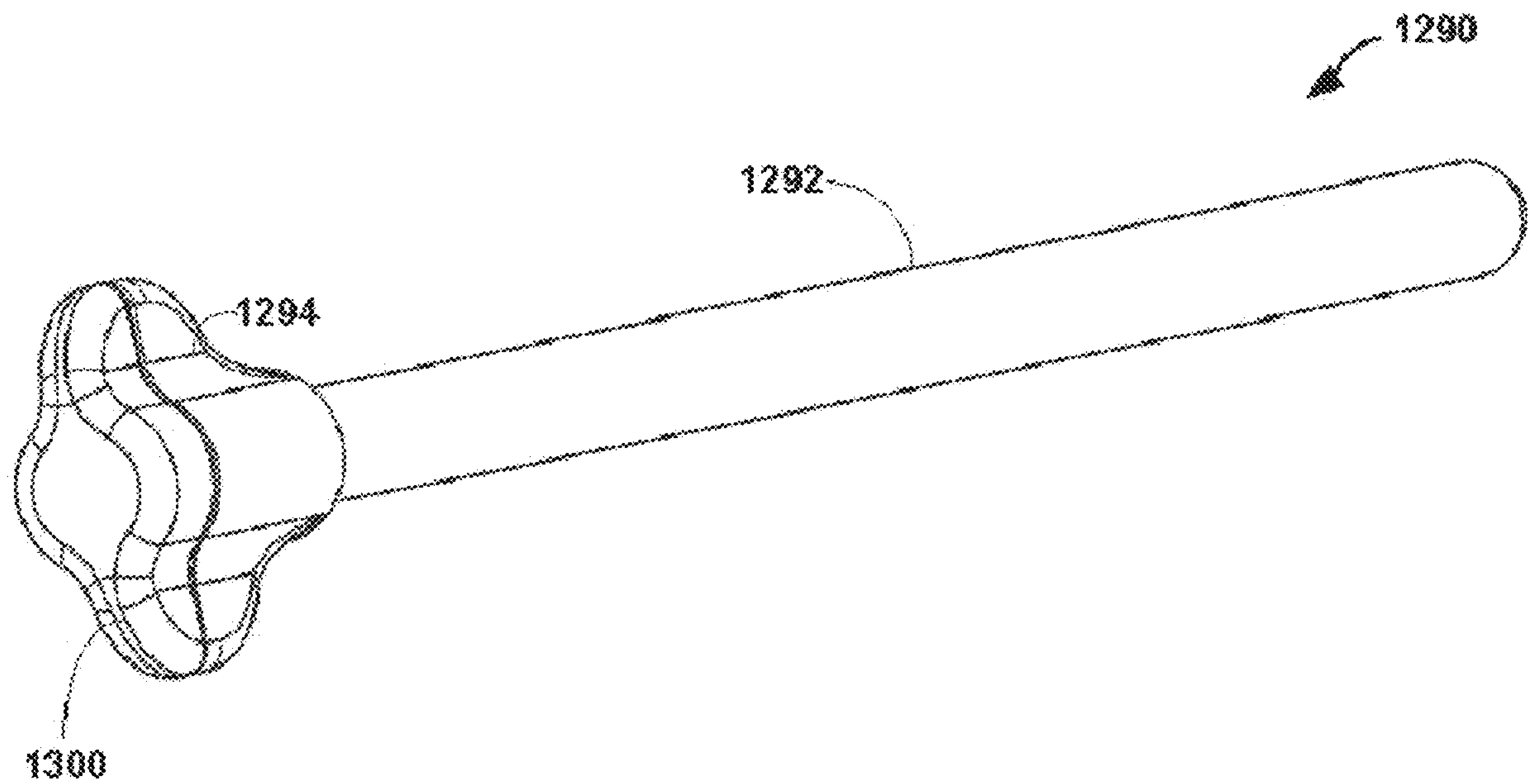
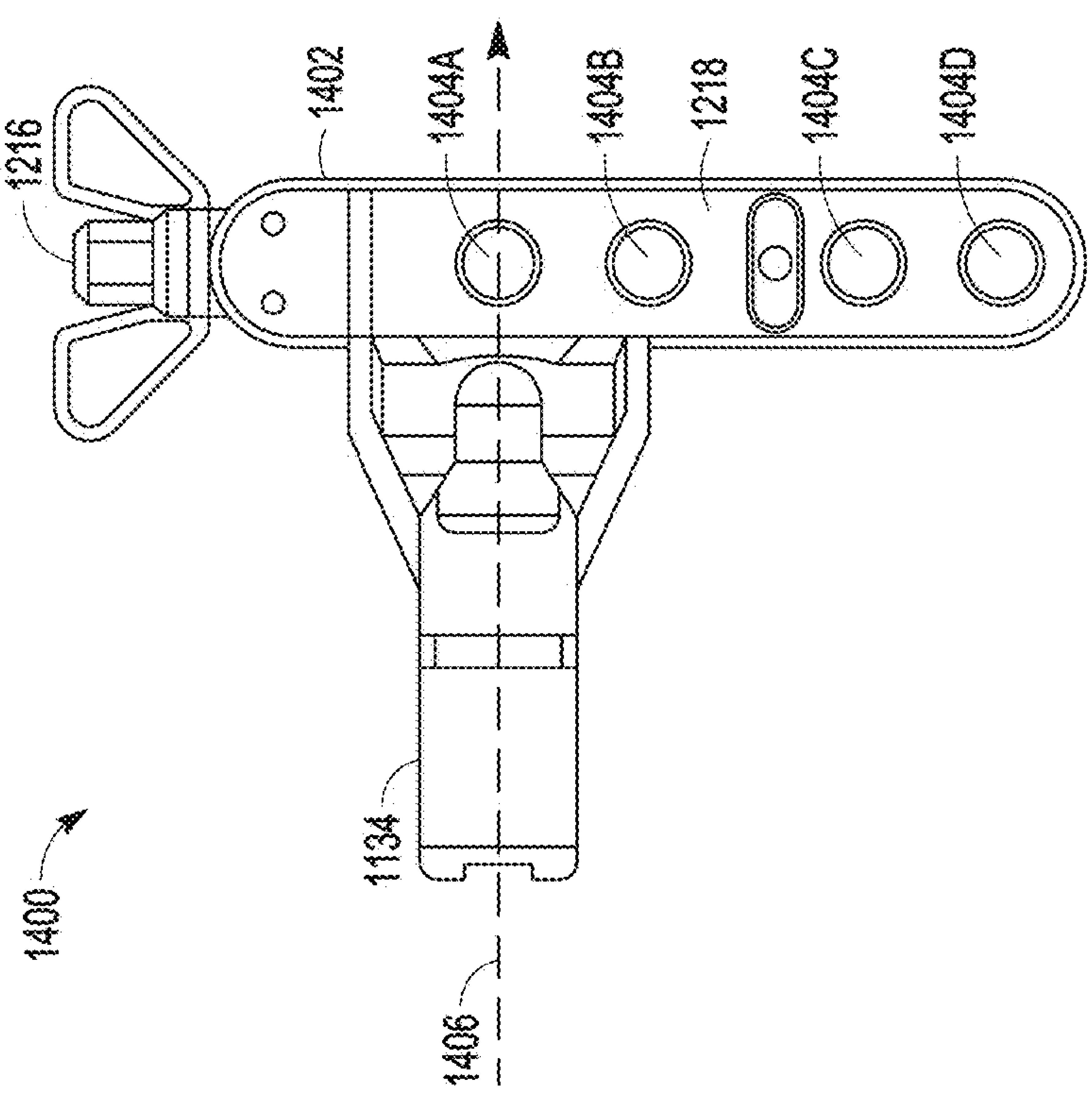


FIG. 47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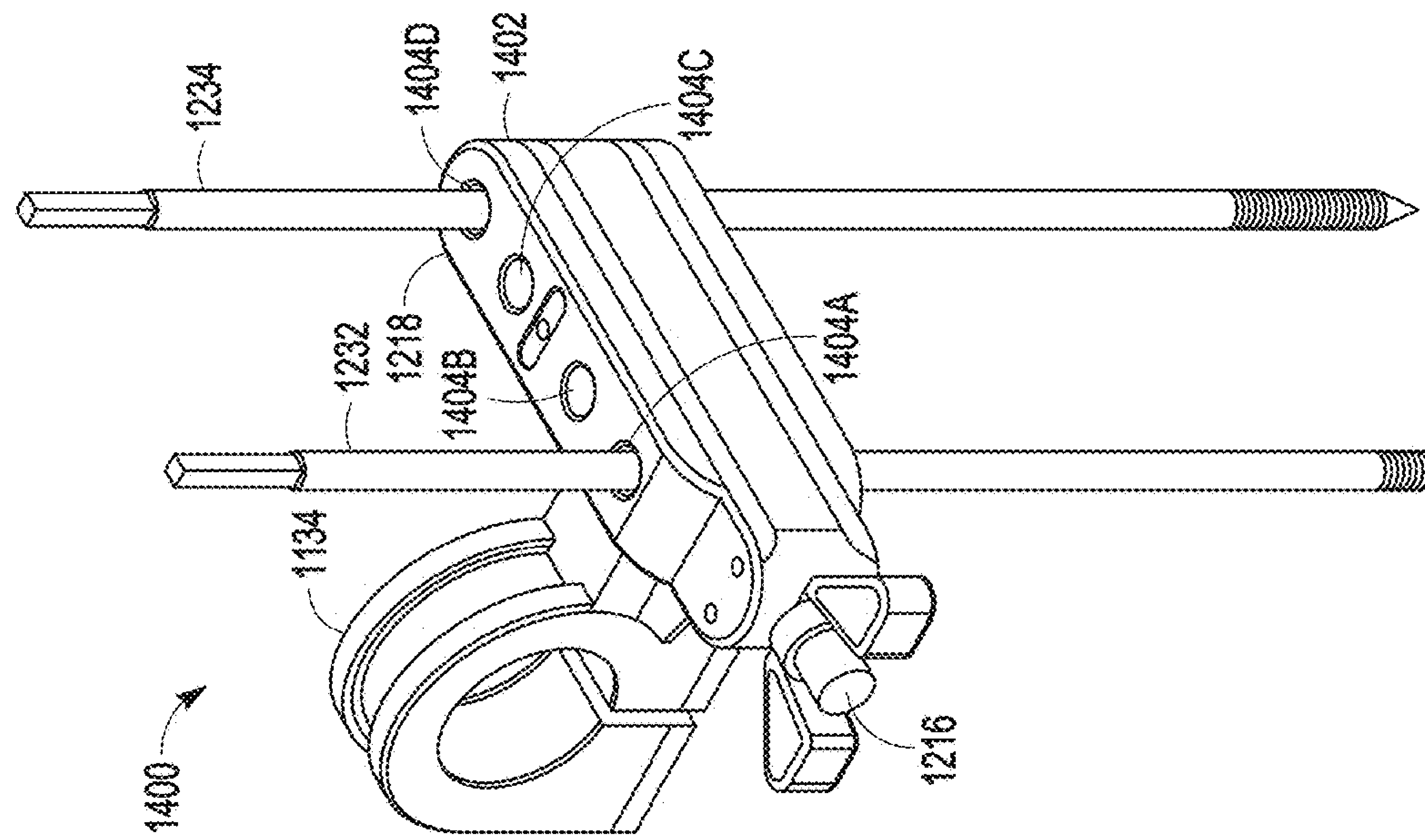
1404C
1404D
1134
1400
1406

FIG. 48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1400
1216

FIG. 49

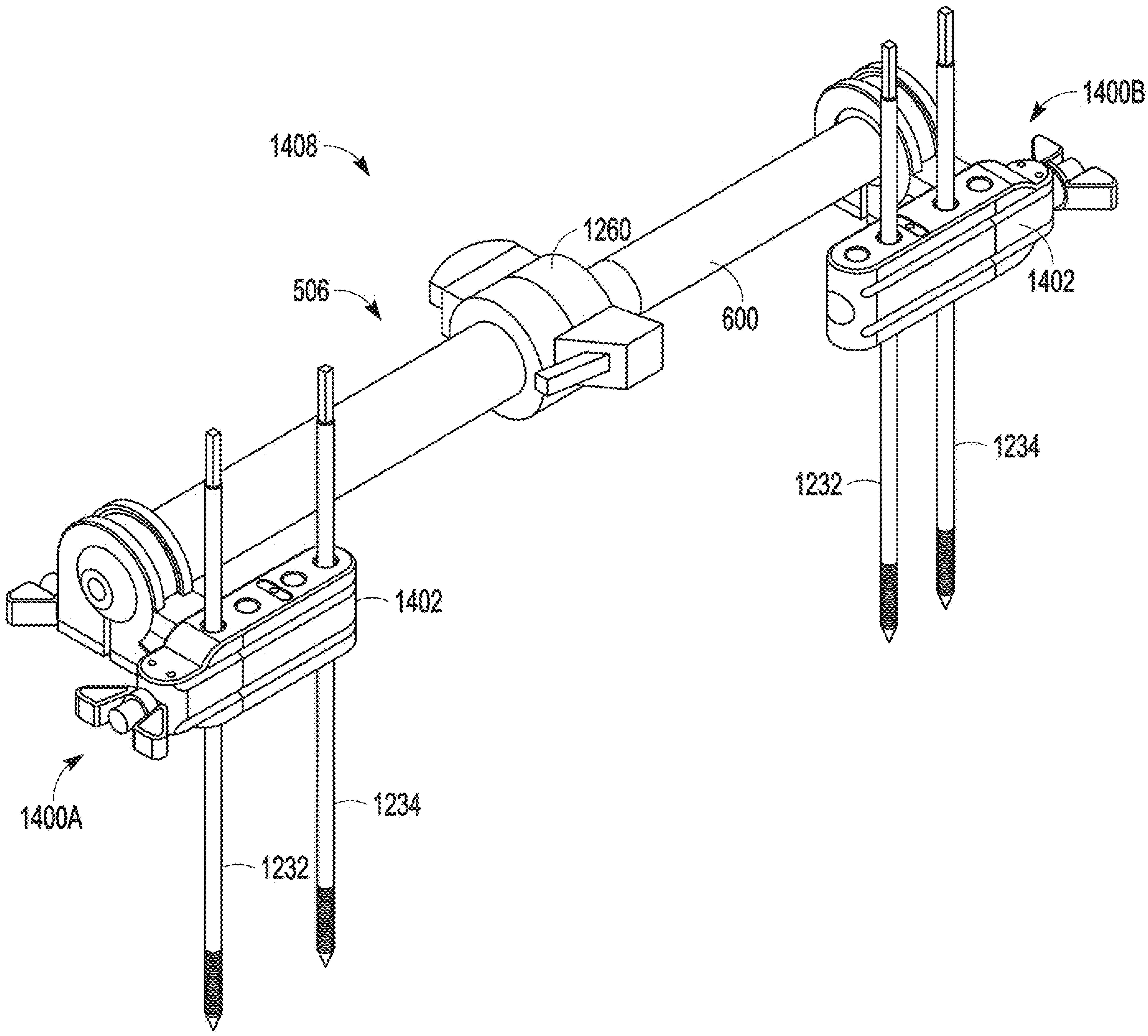

FIG. 50

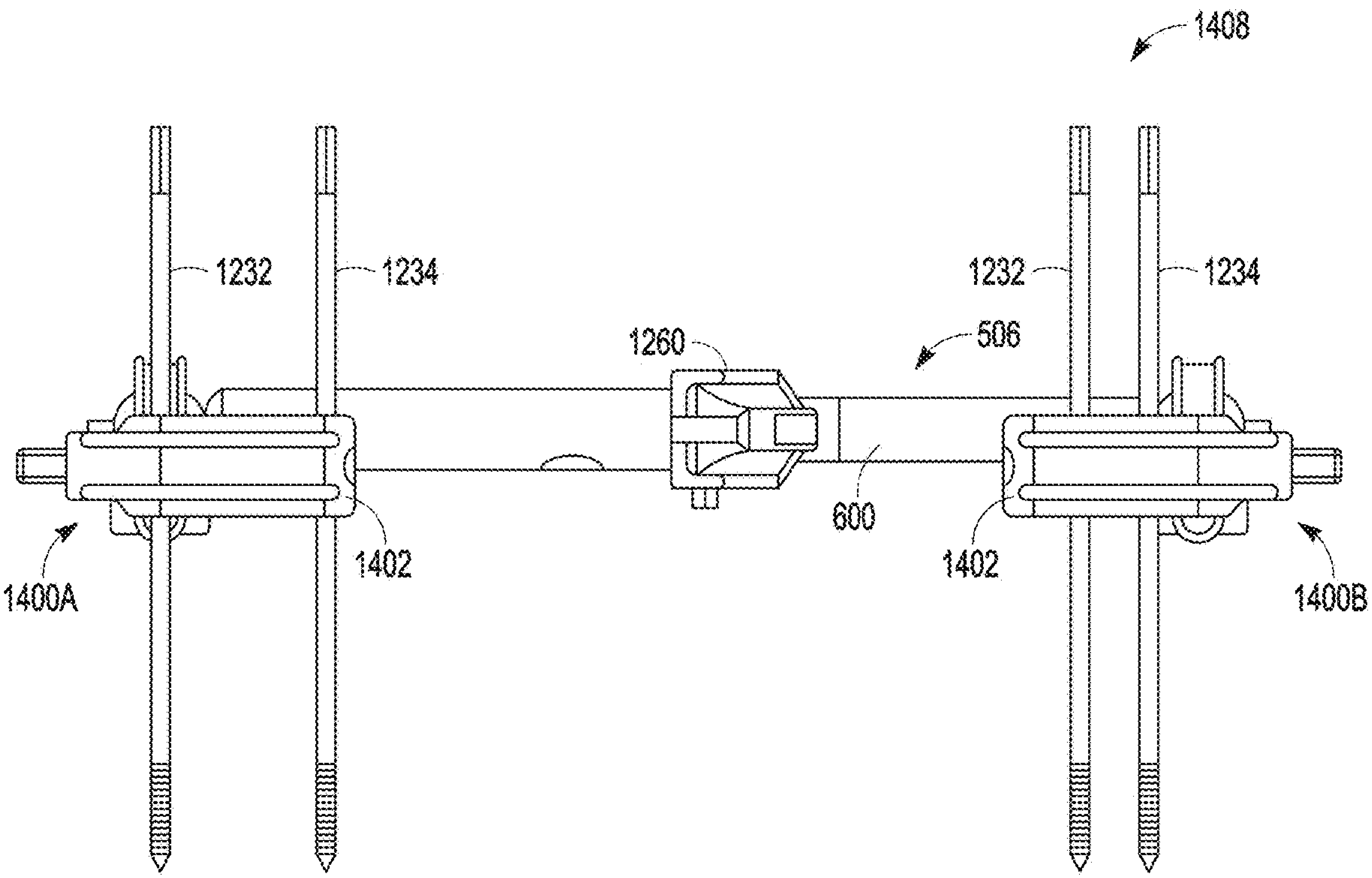
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FIG. 51

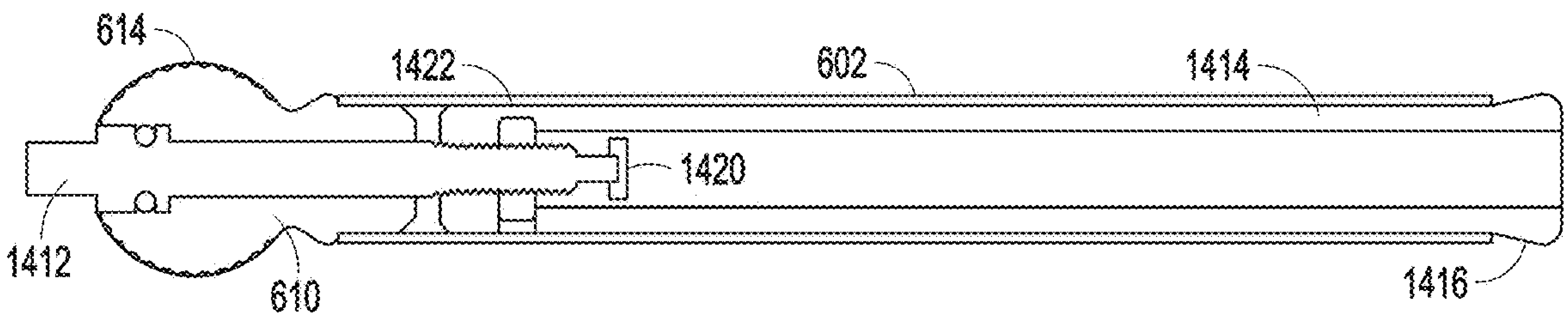
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FIG. 52

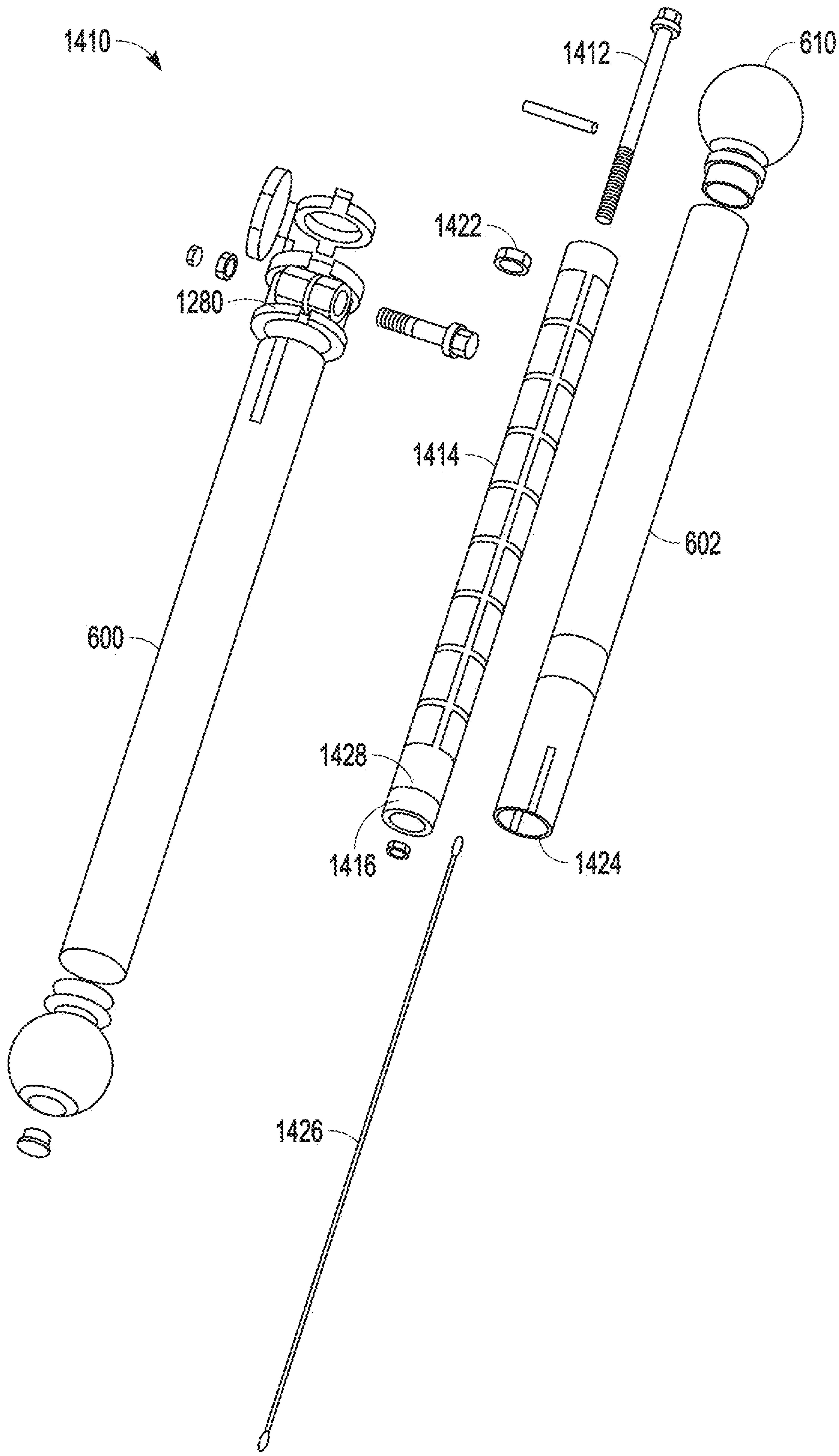

FIG. 53

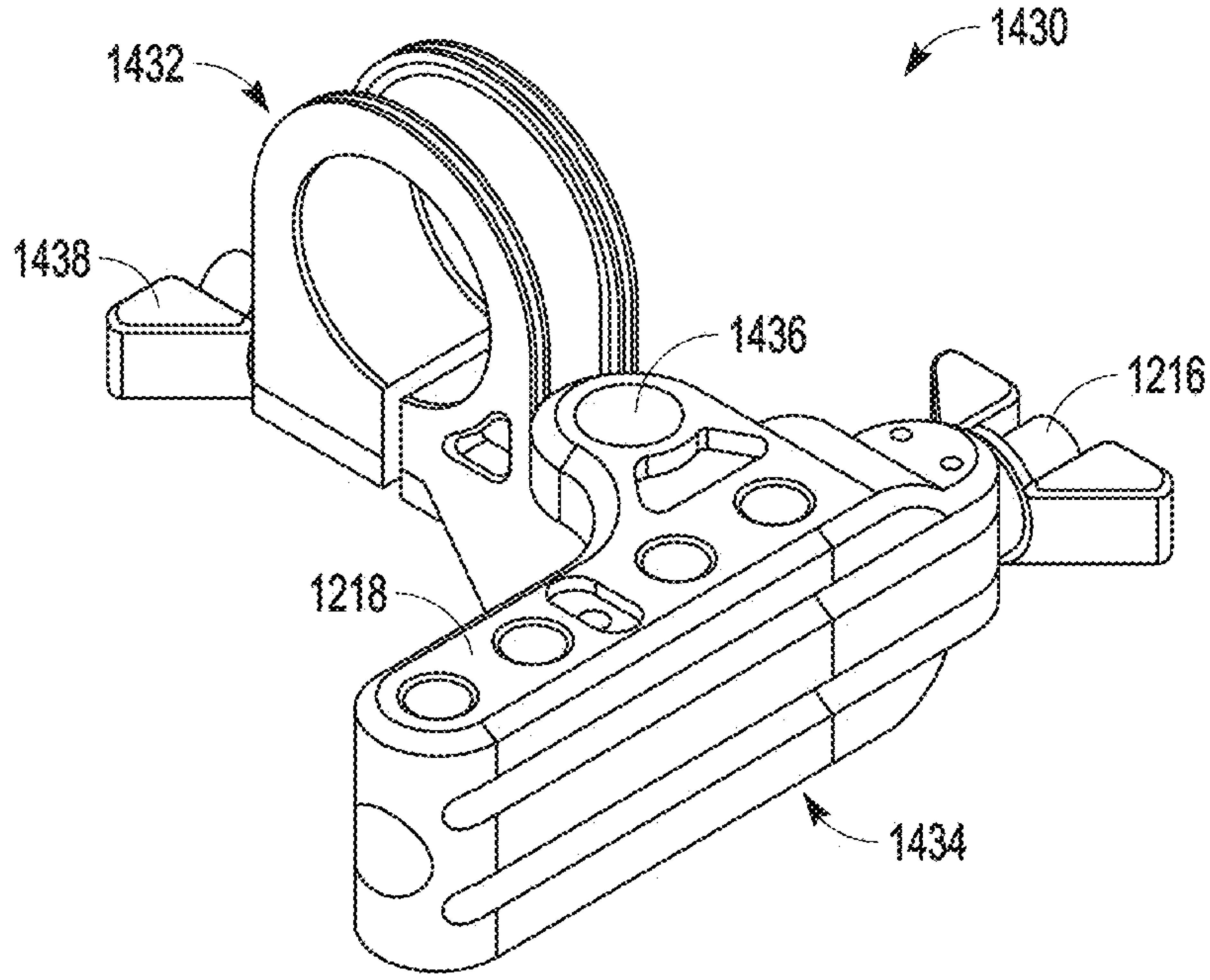

FIG. 54

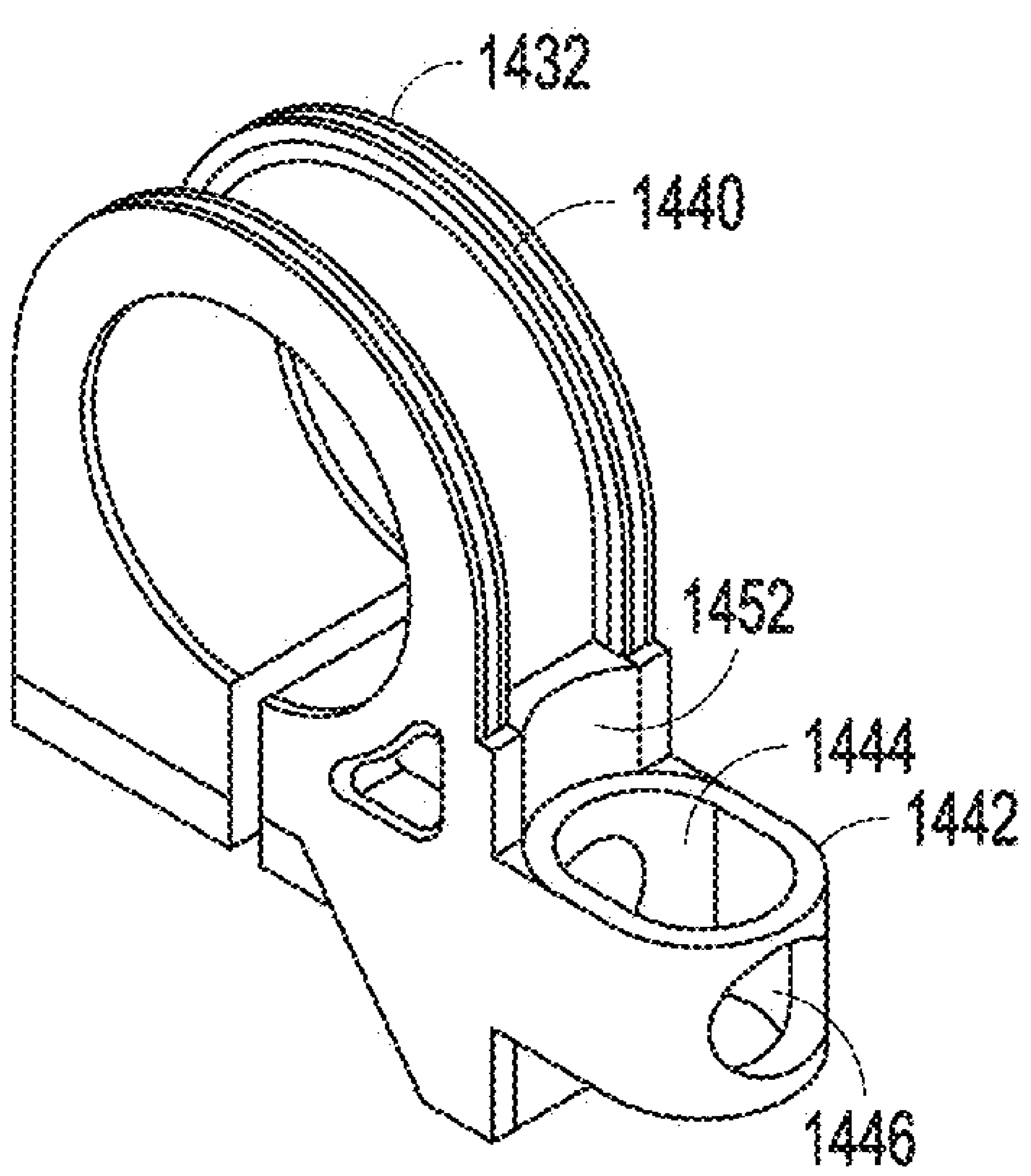

FIG. 55A

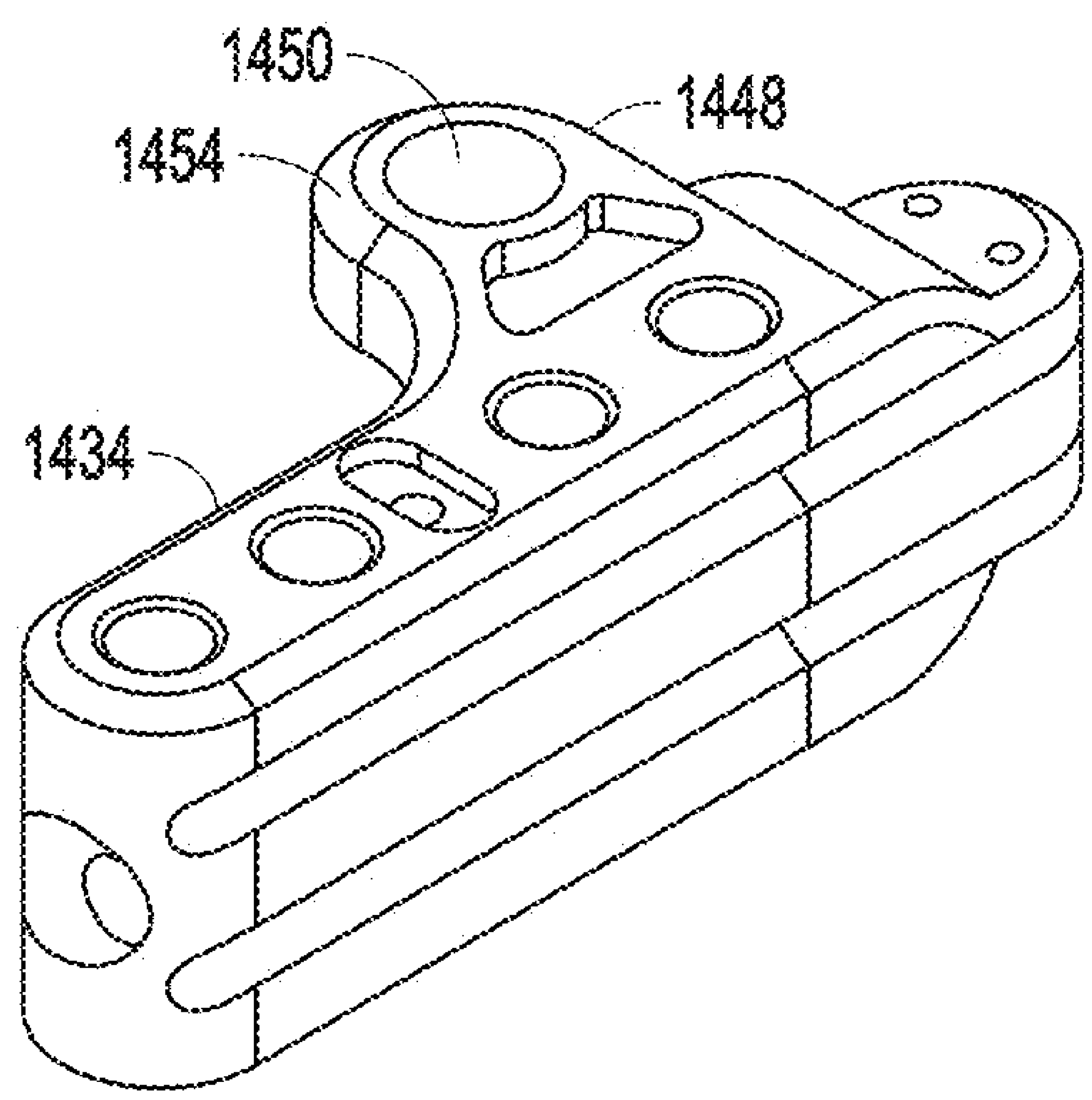

FIG. 55B

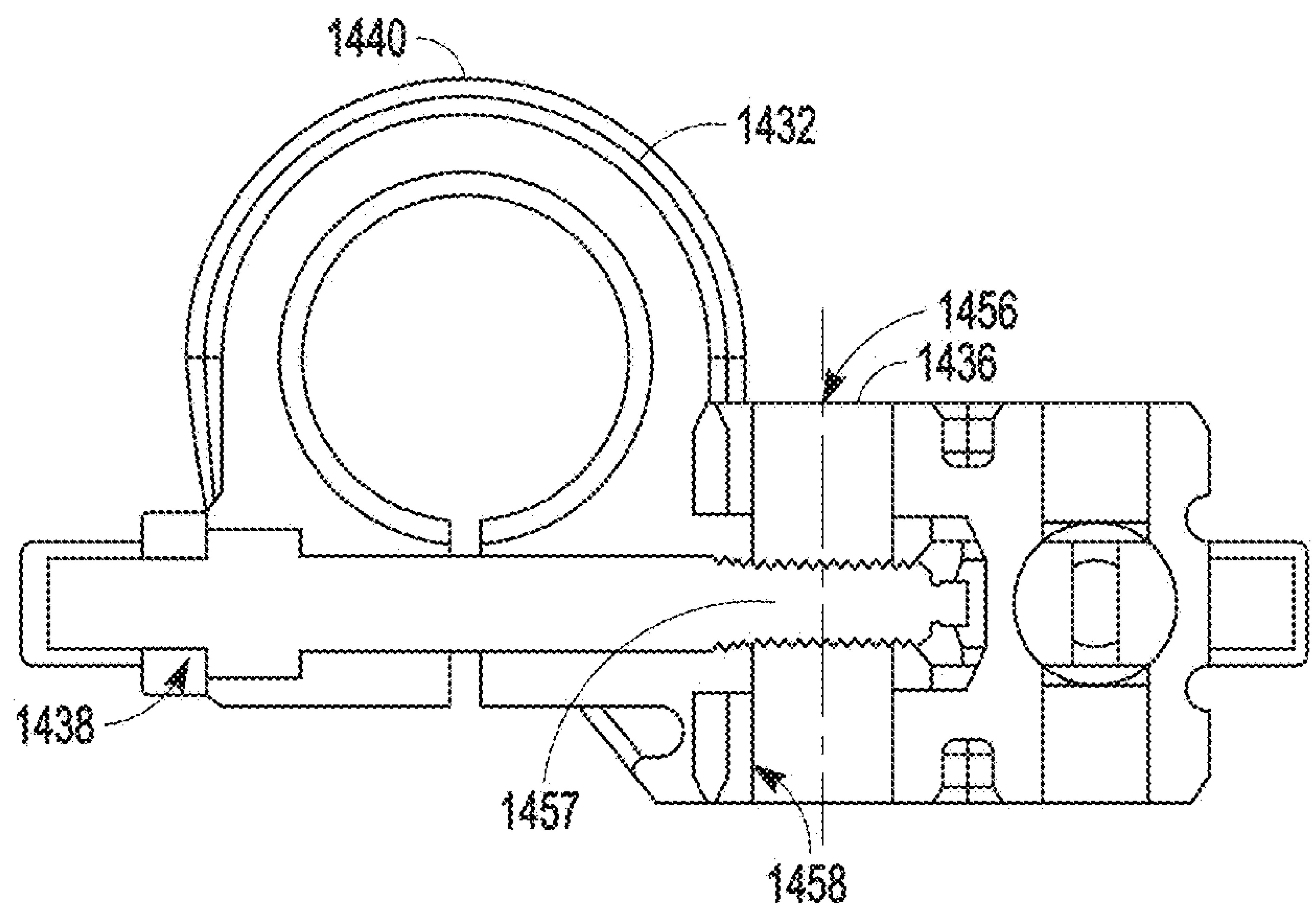
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FIG. 56

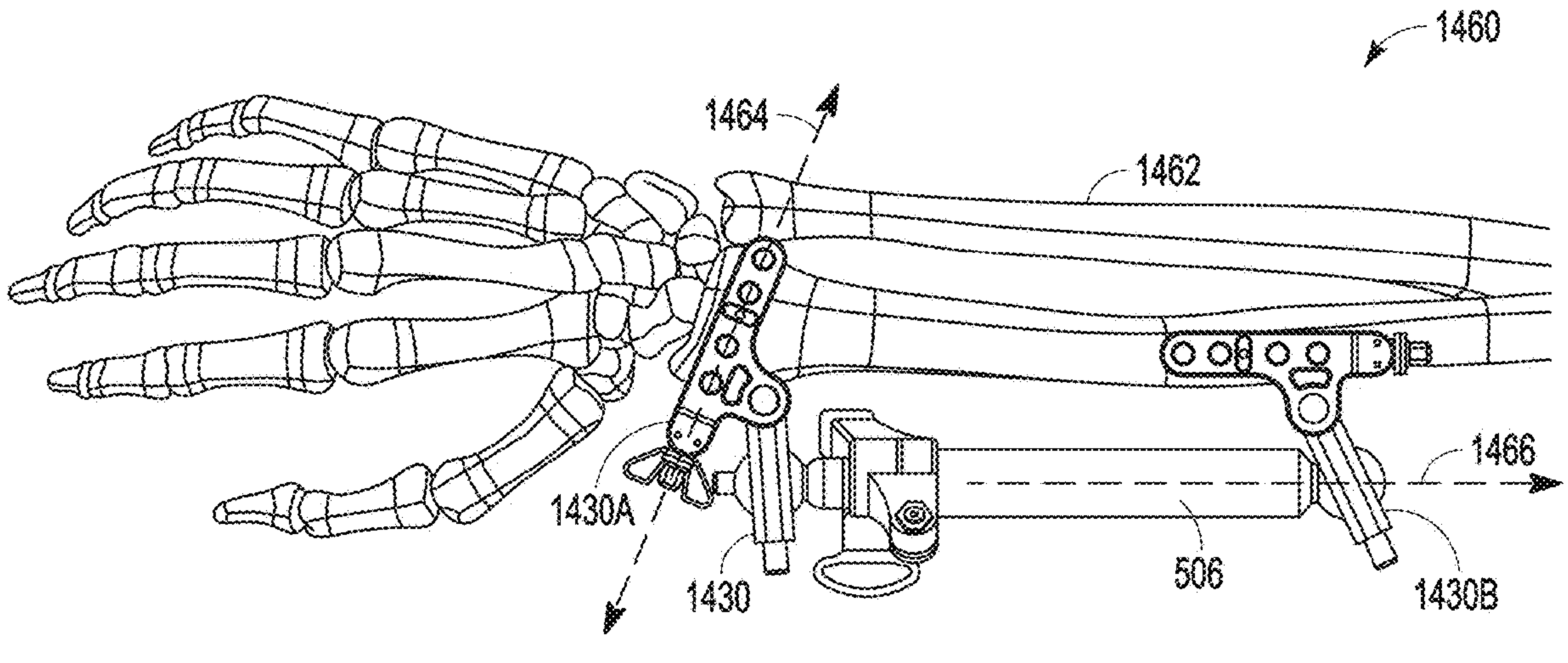
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FIG. 57

EXTERNAL FIXATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This patent application is a divisional of U.S. patent application Ser. No. 14/668,282, filed Mar. 25, 2015, and is titled EXTERNAL FIXATION, which is a continuation-in-part application of U.S. patent application Ser. No. 14/456,407, filed Aug. 11, 2014, and is titled EXTERNAL FIXATION, the entire content of which are being incorporated herein by reference in its entirety, and the benefit of priority of each of which are claimed herein.

TECHNICAL FIELD

This disclosure relates to systems, devices and methods for external fixation. More specifically, this disclosure relates to systems for providing external fixation to joints and/or fractured bones.

BACKGROUND

The present disclosure relates to systems, devices and methods for long bone external fixation, as well as distal radius, ankle, etc. fixation. Bone external fixation is useful in several applications, for example, for use in short-term stabilization of traumatic injuries, long-term stabilization of traumatic injuries, short- or long-term stabilization of a joint, and limb-lengthening stabilization during the healing process.

The systems, devices and methods described herein may be used for stabilization of a traumatic injury until a long-term stabilization device can be applied. Short-term or temporary stabilization may allow soft tissues to recover from trauma prior to definitive skeletal fixation; for example reduction of swelling, healing of open wounds, and/or healing of skin abrasions prior to open reduction and internal fixation. External fixation may also be used when transportation is required from the site of initial care, such as a local or rural hospital to a secondary site with appropriate trauma capabilities, such as a regional trauma center. Short-term stabilization may also be used for injuries that occur during periods of time when appropriate trauma care is not available, such as after hours, until a skilled clinician becomes available. Short-term stabilization may be appropriate in battlefield or field hospital situations. There is a need for external fixation systems and methods which are simple, easy, and affordable.

In fixation systems known in the art, significant time may be spent assembling clamp bodies on the back table. In many cases, the same components are used each time. During implantation over the fracture or joint, sliding rods, moving clamps and other numerous parts requiring individual adjustment make the application and tightening of the frame cumbersome. There is a need for a frame that requires no pre-assembly and can simply be placed over the fracture or joint, have the first set of pins placed on one side of the joint, stretch the frame over the joint and place the second set of pins as desired on the second side of the joint. There would be no assembly and no possibility of rods sliding out of the clamps in such an arrangement.

In many situations, before an external fixation frame can be locked down, the fracture/joint must be restored to its proper length. In order to do this, the limb must be stretched against the natural tension in the muscles. This force is significant, as some surgeons report that they pull until "their feet begin to slide on the floor". In systems known in the art, the surgeon must hold this tension as an assistant tightens all the clamps in the frame. There is a need for a one-way motion lock that holds the limb length once it has been established. This would allow the surgeon to make minor adjustments as necessary and lock the frame in a less technically demanding manner and potentially without as much assistance from other scrubbed personnel as is needed with systems known in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope.

FIG. **1** is a perspective view of an external fixation system including a first clamping assembly, a second clamping assembly, and two rod assemblies captured in the first and second clamping assemblies, the external fixation system mounted on a plurality of bone pins.

FIG. **2** is a top-down view of the external fixation system of FIG. **1**.

FIG. **3** is an enlarged perspective view of the first clamping assembly of FIG. **1**, including two bone pins.

FIG. **4** is an exploded view of a clamping assembly of FIG. **1**.

FIG. **5** is a cross-sectional view of the clamping assembly of FIG. **1** taken along line A-A of FIG. **2**.

FIG. **6** is a cross-sectional view of the clamping assembly of FIG. **1** taken along line B-B of FIG. **2**.

FIG. **7** is a perspective view of a rod assembly of FIG. **1**.

FIG. **8** is an exploded view of the rod assembly of FIG. **1**.

FIG. **9** is a longitudinal cross-sectional view of a rod assembly of FIG. **1** taken along line C-C of FIG. **2**.

FIG. **10** is an end view of a rod assembly of FIG. **1**, with a tube plug removed in order to show detail of a locking clamp.

FIG. **11** is a top-down view of a kit including a tray, the external fixation system of FIG. **1**, a plurality of bone pins, a drill guide, drill sleeves, and a wrench.

FIG. **12** is a perspective view of another external fixation system, secured to a tibia, a calcaneus, and a metatarsal to span an ankle joint, the system including a clamping assembly, two rod assemblies, two clamping strut assemblies, a pin clamp assembly, a spanning member and a plurality of bone and calcaneal pins.

FIG. **13** is a side view of the external fixation system of FIG. **12** secured to the tibia, calcaneus, and metatarsal.

FIG. **14** is a perspective view of the external fixation system of FIG. **12**.

FIG. **15**A is a side view of a clamping strut of the external fixation system of FIG. **12**; FIG. **15**B is a posterior perspective view of the clamping strut of FIG. **15**A.

FIG. **16** is an exploded anterior perspective view of a clamping strut assembly of the system of FIG. **12**.

FIG. **17**A is an anterior view of the spanning member of the system of FIG. **12**; FIG. **17**B is a posterior view of the spanning member; FIG. **17**C is a superior view of the spanning member.

FIG. **18**A is a side view of the pin clamp assembly of FIG. **12**; FIG. **18**B is a top view of the pin clamp assembly.

FIG. **19** is an anterior perspective view of a two-level external fixation system mounted to span a knee joint and an ankle joint, the system including the knee spanning external fixation system of FIG. **1** and the ankle spanning external fixation system of FIG. **12** in a stacked configuration, mounted on a common set of tibial bone pins.

FIG. **20** is a side view of the two-level external fixation system of FIG. **19**.

FIG. **21** is a perspective view of yet another external fixation system, the system including two clamping assemblies, a rod assembly, and a plurality of bone pins.

FIG. **22** is a perspective view of a clamping assembly and bone pins of the external fixation system of FIG. **21**.

FIG. **23** is an exploded perspective view of the clamping assembly and bone pins of FIG. **22**.

FIG. **24** is another exploded perspective view of the clamping assembly and bone pins of FIG. **22**, from a different viewpoint.

FIG. **25** is a cross-sectional view of the clamping assembly of FIG. **22**, comparable to FIG. **5**.

FIG. **26** is another cross-sectional view of the clamping assembly of FIG. **22**, comparable to FIG. **6**.

FIG. **27** is a perspective view of the external fixation system of FIG. **21** secured to a radius and a metacarpal to span a wrist joint.

FIG. **28** is a perspective view of another clamping assembly, including two bone pins.

FIG. **29** is a top view of a portion of the main clamp body depicted in FIG. **28**, depicting the sliding clamp in an open position.

FIG. **30** is a top cross-sectional view of the portion of the main clamp body depicted in FIG. **29**, depicting the sliding clamp in an open position.

FIG. **31** is a top view of a portion of the main clamp body depicted in FIG. **28**, depicting the sliding clamp in a closed position.

FIG. **32** is a cross-sectional view of an example portion of the main clamp body of FIG. **29**.

FIG. **33** is a cross-sectional view of the clamping assembly of FIG. **28**.

FIGS. **34**A and **34**B depict another example of a sliding clamp that can be used in accordance with various techniques of this disclosure.

FIGS. **35**A and **35**B depict another example of a sliding clamp that can be used in accordance with various techniques of this disclosure.

FIG. **36** depicts another example of a sliding clamp that can be used in accordance with various techniques of this disclosure.

FIG. **37** depicts another example of a sliding clamp that can be used in accordance with various techniques of this disclosure.

FIG. **38** is a cross-sectional view of another example of a clamp assembly.

FIG. **39** is a top view of the flexible plate of FIG. **38**.

FIG. **40** is a perspective view of another example of a rod clamp assembly.

FIG. **41** is a cross-sectional side view of the rod clamp assembly of FIG. **40** in combination with a rod.

FIG. **42** is a perspective view of a portion of a rod assembly including the rod clamp assembly of FIG. **40**.

FIG. **43** is an exploded view of a trocar assembly.

FIGS. **44**A-**44**C are perspective views of the first grip and the second grip of the trocar assembly of FIG. **43**.

FIG. **45** is a perspective view of the trocar assembly of FIG. **43** in an interlocked position.

FIGS. **46**A-**46**C are perspective views of another example of a first grip and a second grip that can be used with a trocar assembly.

FIG. **47** is a perspective view of a trocar assembly depicting the first and second grips of FIGS. **46**A-**46**C in an interlocked position.

FIG. **48** is a top view of another example of a clamping assembly of the external fixation system.

FIG. **49** is a perspective view of the clamping assembly of FIG. **48** with bone pins depicted.

FIG. **50** is a perspective view of an example of an external fixation system, the system including two clamping assemblies of FIG. **48**, a rod assembly, and a plurality of bone pins.

FIG. **51** is a side view of the external fixation system of FIG. **50**.

FIG. **52** is a cross-sectional view of an example of an expansion plug of a rod assembly, in accordance with this disclosure.

FIG. **53** is an exploded view of a rod assembly including the expansion plug of FIG. **52**.

FIG. **54** is a perspective view of an example of a hinged main clamp body.

FIGS. **55**A and **55**B are perspective views of a clamp hoop body and the main clamp body of FIG. **54**, respectively.

FIG. **56** is a cross-sectional view of the example of the hinged main clamp body of FIG. **54**.

FIG. **57** is a perspective view of an external fixation system, secured to a radius of an arm.

DETAILED DESCRIPTION

The present disclosure relates to external fixation systems and methods for their use. Those of skill in the art will recognize that the following description is merely illustrative of the principles of the technology, which may be applied in various ways to provide many different alternative embodiments. This description is made for the purpose of illustrating the general principles of this technology and is not meant to limit the inventive concepts in the appended claims. While the present disclosure is made in the context of knee or ankle joint or fracture fixation for the purposes of illustrating the concepts of the design, it is contemplated that the present design and/or variations thereof may be suited to applications in the arm, wrist, finger, toe, spine, or other bones or joints.

The technology described herein may relate to an external fixation clamp that utilizes at least one polyaxial joint to provide for a highly adaptable connection between a bone and a stiffening rod.

The devices, kits and methods of the present disclosure can provide an external fixation system which is economically disposable. The systems of the present disclosure may be manufactured at such a low cost that they can be considered disposable after one use. For example, a kit of the present disclosure may be made for a manufacturer's suggested retail price (MSRP) of about $500. Each of the external fixation systems disclosed herein may be provided pre-assembled in a kit which may also include tools and/or fixation members such as pins. In a method of use, bone pins may be fixed in bone portions of a patient, to span a fracture and/or an anatomical joint. The pre-assembled external fixation system is mounted on the bone pins as a single piece or unit, and provisionally locked by pulling one end of the system away from the opposite end, thus setting the fracture and/or immobilizing the anatomic joint. After the provisional locking, which holds the joint or fracture immobilized, individual connections and clamps of the system may be adjusted and further locked down. The external fixation system may remain on the patient for a short term period of time which may include transportation time. For example, a complex ankle fracture such as a pylon (pilon) fracture might be initially treated with an external fixator until swelling lessens one or two weeks later and it is safer to make skin incisions to treat the fracture definitively. The patient might be transported to another hospital or rehabilitation facility between the time of initial external fixator placement and definitive surgery. In another example, one or more systems of the present disclosure may be used on a patient in a battlefield or at an accident site, and left in the locked down configuration on the patient through transportation to a hospital, where surgery or other long-term means are used to stabilize the fracture or joint.

In this specification, standard medical directional terms are employed with their ordinary and customary meanings. Superior means toward the head. Inferior means away from the head. Anterior means toward the front. Posterior means toward the back. Medial means toward the midline, or plane of bilateral symmetry, of the body. Lateral means away from the midline of the body. Proximal means toward the trunk of the body. Distal means away from the trunk.

In this specification, a standard system of three mutually perpendicular reference planes is employed. A sagittal plane divides a body into bilaterally symmetric right and left portions. A coronal plane divides a body into anterior and posterior portions. A transverse plane divides a body into superior and inferior portions.

In an aspect of a method for external fixation of a limb, the limb having a first bone portion and a second bone portion, the method includes: securing a first bone pin to the first bone portion; securing a second bone pin to the second bone portion; attaching a pre-assembled external fixation system to the first bone pin, the external fixation system including: first and second clamp assemblies, first rod assemblies, and a one-way locking mechanism; the first rod assembly joined to each of the first and second clamp assemblies, the first and second clamp assemblies at opposite longitudinal ends of the first rod assemblies; the first clamp assembly received over the first bone pin; attaching the external fixation system to the second bone pin, the second clamp assembly received over the second bone pin; applying tension to distract the first clamp assembly longitudinally away from the second clamp assembly to increase a length of the external fixation system between the first clamp assembly and the second clamp assembly; and releasing the tension on the first clamp assembly, wherein when the tension on the first clamp assembly is released the one-way locking mechanism automatically engages to prevent the length of the external fixation system from decreasing.

In an embodiment, the method may include: opening a package; and removing the pre-assembled external fixation system as a single unit from the package

In another embodiment, each rod assembly includes a removable tab, the method including: removing the tab to activate the one-way locking mechanism, wherein prior to removal of the tab, the external fixation system is freely adjustable to increase or decrease the length of the external fixation system between the first clamp assembly and the second clamp assembly;

In yet another embodiment, the external fixation system includes a second rod assembly, the second rod assembly joined to each of the first and second clamp assemblies.

In yet another embodiment, the first clamp assembly is identical to the second clamp assembly, and the first rod assembly is identical to the second rod assembly.

In yet another embodiment, the one-way locking mechanism automatically engages the rod assembly to prevent the length of the external fixation system from decreasing.

In yet another embodiment, the one-way locking mechanism automatically engages the rod assembly at a non-discrete location to prevent the length of the external fixation system from decreasing.

In yet another embodiment, the rod assembly includes an inner tubular member received in an outer tubular member, wherein the one-way locking mechanism is a first locking mechanism, wherein the one-way locking mechanism is mounted to the outer tubular member, wherein activating the one-way locking mechanism further includes: directly engaging the one-way locking mechanism with the inner tubular member to prevent the inner tubular member from translating relative to the outer tubular member in a first direction.

In yet another embodiment, the one-way locking mechanism includes a collar encircling the inner tubular member, wherein the collar frictionally engages with the inner tubular member to prevent the inner tubular member from translating relative to the outer tubular member in the first direction.

In yet another embodiment, the method includes: activating a second locking mechanism to further prevent the inner tubular member from translating relative to the outer tubular member in the first direction and also in a second direction opposite the first direction.

In yet another embodiment, the rod assembly further includes the second locking mechanism, the second locking mechanism including a clamp encircling the outer tubular member, the method further including: compressing the clamp around the outer tubular member; and compressing the outer tubular member around the inner tubular member.

In yet another embodiment, the method includes: activating a third locking mechanism to further prevent the inner tubular member from translating relative to the outer tubular member.

In yet another embodiment, the rod assembly further includes the third locking mechanisms, the third locking mechanism including a plug received in the inner tubular member, the method further including drawing the plug within the inner tubular member to expand a portion of the inner tubular member.

In yet another embodiment, the method includes: polyaxially adjusting the position of the first rod assembly relative to the first clamp assembly; and compressing the first clamp assembly about the first rod assembly to lock the position of the first rod assembly relative to the first clamping assembly.

In yet another embodiment, the method includes: locking the first clamping assembly to the first bone pin.

In yet another embodiment, the first clamping assembly houses a first fixation plate and a second fixation plate, wherein locking the first clamping assembly to the first bone pin further includes: passing the first bone pin through the first and second fixation plates; and deforming the first and second fixation plates to bind against the first bone pin.

In yet another embodiment, the method includes: passing a third bone pin into the first clamping assembly; and securing the third bone pin to the limb.

In an aspect of an external fixation system, the system includes: a first clamp assembly; a second clamp assembly; a first rod assembly secured to and extending between the first clamp assembly and the second clamp assembly, the first rod assembly including a first tubular member and a second tubular member received in the first tubular member; and a one-way locking mechanism which limits axial translation between the first tubular member and the second tubular member, the one-way locking mechanism having an unlocked configuration and a locked configuration; wherein the external fixation system has a length measured between the first clamp assembly and the second clamp assembly; wherein when the one-way locking mechanism is in the unlocked configuration the second tubular member can freely translate relative to the first tubular member to increase or decrease the length of the external fixation system; and wherein when the one-way locking mechanism is in the locked configuration second tubular member can freely translate relative to the first tubular member to increase the combined length of the external fixation system but is prevented from translating relative to the first tubular member to decrease the length of the external fixation system.

In an embodiment, the external fixation system includes a second rod assembly secured to and extending between the first clamp assembly and the second clamp assembly, wherein the first clamp assembly is identical to the second clamp assembly, and wherein the first rod assembly is identical to the second rod assembly.

In another embodiment, the second tubular member can axially translate in a first direction to increase the length of the external fixation system and in a second direction opposite the first direction to decrease the length of the external fixation system.

In yet another embodiment, in the locked configuration the one-way locking mechanism engages the first rod assembly to prevent the length of the external fixation system from decreasing.

In yet another embodiment, the one-way locking mechanism further includes a collar encircling the second tubular member, wherein, in the locked configuration, the collar binds against the second tubular member to prevent translation of the second tubular member in the second direction.

In yet another embodiment, the one-way locking mechanism is a first locking mechanism, the system further including a second locking mechanism to further prevent the second tubular member from any motion relative to the first tubular member.

In yet another embodiment, the rod assembly further includes the second locking mechanism, the second locking mechanism including a clamp encircling the first tubular member, wherein the clamp is compressible about the first tubular member to compress the first tubular member around the second tubular member to prevent any motion relative to the first tubular member.

In yet another embodiment, the external fixation system includes a third locking mechanism which engages the first and second tubular members.

In yet another embodiment, the third locking mechanism includes a plug received in the second tubular member, wherein drawing the plug within the second tubular member expands a portion of the second tubular member to fit tightly within the first tubular member.

In yet another embodiment, the first clamp assembly includes a spherical clamping surface and the first rod assembly includes a spherical portion, the spherical portion received within the spherical clamping surface to form a polyaxial joint between the first clamp assembly and the first rod assembly.

In yet another embodiment, the first clamp assembly further includes a locking screw, wherein tightening the locking screw compresses the spherical clamping surface around the spherical portion to lock the position of the first rod assembly relative to the first clamping assembly.

In yet another embodiment, the external fixation system includes a second rod assembly including a second spherical portion, wherein the first clamping assembly further includes a second spherical clamping surface, the second spherical portion received within the second spherical clamping surface to form a polyaxial joint between the first clamp assembly and the second rod assembly, wherein tightening the locking screw simultaneously locks the positions of the first and second rod assemblies relative to the first clamping assembly.

In yet another embodiment, the external fixation system includes a first bone pin, wherein the first clamping assembly houses a first fixation plate and a second fixation plate, wherein the first bone pin passes through the first fixation plate and the second fixation plate, and the first and second fixation plates are deformable to bind against the first bone pin and fix the position of the first bone pin relative to the first clamping assembly.

In yet another embodiment, the external fixation system includes a removable tab attached to the one-way locking mechanism, wherein the removable tab holds the one-way locking mechanism in the unlocked configuration, wherein removal of the tab from the one-way locking mechanism converts the one-way locking mechanism to the locked configuration.

Referring to FIGS. **1** and **2**, an external fixation system **500** includes a first clamping assembly **502**, a second clamping assembly **504**, a first rod assembly **506** and a second rod assembly **508**. In an embodiment, external fixation system **500** may be referred to as a knee spanning system or joint spanning system, although external fixation system **500** may also be used to span a fracture, osteotomy, epiphyseal plate, or other discontinuity between bone portions. The rod assemblies **506**, **608** extend between and connect the clamping assemblies **502**, **504** into the single system **500**. The rod assemblies **506**, **508** may be scaled to an appropriate size for the knee or other anatomical site. In some embodiments, the second rod assembly **508** may be omitted. The connections between the rod assemblies and clamping assemblies are polyaxially adjustable. The clamping assemblies may be referred to as support elements or members, as they support the rod assemblies. The rod assemblies may be referred to as variable length or telescoping elements, struts, or members, as the length of each is adjustable. The external fixation system **500** may be referred to as a frame. The first and second clamping assemblies may be mirror images, or may be identical to one another, as may the first and second rod assemblies. Using identical assemblies in a system may enable the entire system to be produced more cheaply and/or quickly than a system in which each separate component or assembly is unique. For example the system **500** with identical assemblies **502**, **504** and **506**, **508** may require fewer forms and unique production processes than a system having multiple unique and non-identical components. Assembly may also be faster as there may be fewer steps, and certain assembly steps may be repeated.

In use, system **500** can be secured to the patient in one piece, as a unit. First clamping assembly **502** may be fixed to a first bone portion by one or more fixation pins **510**. Bone screws, bone pins, wires, and/or other fasteners may be used in place of or in combination with fixation pins **510**. Second clamping assembly **504** may be fixed to a second bone portion by additional fixation pin(s) **510**. The rod assemblies **506** and **508**, extending between the clamping assemblies, may span a joint or fracture between the first and second bone portions. After the clamping assemblies **502**, **504** are fixed to the bone portions, the rod assemblies **506**, **508** may be lengthened or shortened to a desired length and provisionally locked to stabilize the joint or fracture. Following the provisional locking, the polyaxial connections of the assembly may be adjusted, then more permanently locked.

Referring to FIGS. **3-6**, clamping assembly **502** is shown in more detail. Clamping assembly **504** may be a mirror image, or may be identical to clamping assembly **502** and will not be described in further detail; the description of clamping assembly **502** also applies to clamping assembly **504**. Clamping assembly **502** includes a clamp body **520** which is formed as a single piece. Clamping assembly **502** further includes first and second fixation bolts **522**, **524**; first, second, third and fourth fixation plates **526**, **527**, **528** and **529**; a clamping bolt **530**; first nut **532**; and second nut **533**. The fixation plates may be referred to as locking plates. The rod assemblies **506**, **508** are polyaxially adjustably connected to the clamping assembly **502** via a first clamp **534** and a second clamp **536** which are formed as part of the clamping body **520**. In some embodiments, the second clamp **536** may be omitted. Two bone pins **560**, **562** extend through the clamping body **520** to fix the clamping assembly **502** to a bone portion. In another embodiment, only one bone pin may be used.

Referring to FIGS. **2**, **4** and **5**, clamp body **520** may be cruciform or plus-shaped and includes an upper or first surface **512** and a lower or second surface **514** opposite the first surface. The clamp body **520** further includes a first arm **538** and a second arm **540** which extend along a first axis **541**, perpendicular to the first and second clamps **534**, **536** which extend along a second axis **535**. First axis **541** may be parallel to the longitudinal lengths of rod assemblies **506**, **508** when the system **500** is in a neutral or orthogonal arrangement. Two bolt openings **544**, **546** extend through the clamping body **520** in the same direction as the pin openings **542**, **552** described below. In the example shown, the bolt and pin openings extend in a direction perpendicular to the first axis **541** and the second axis **535**. A first slot **548** is recessed into the first surface **512**, and a second slot **550** is recessed into the second surface **514**, opposite the first slot. The first and second slots are elongated, occupying the majority of the length of the first and second arms **538**, **540**, and slots are parallel with first axis **541**. A plurality of pin openings or bores **542** extend through the arms between the first and second slots **548**, **550**, each pin bore sized to receive a bone pin **510**. First and second fixation plates **526**, **528** are housed in the first slot **548**, and third and fourth fixation plates are housed in the second slot **550**. Each fixation plate **526**, **527**, **528** and **529** includes at least one plate pin opening **552**, and one of a threaded plate bolt opening **554** or a non-threaded plate bolt opening **555**. Each fixation plate **526**, **527**, **528** and **529** is elongated, having a first extension **556** and a second extension **558**.

The bone pins **560**, **562** are received in pin openings **542** of clamp body **520**. As seen in FIGS. **4** and **5**, each bone pin may pass through a plate pin opening **552** in a fixation plate, through the first slot **548**, through a pin bore **542**, through the second slot **550**, and out through a plate pin opening **552** in another fixation plate. The opening for the pins may be non-threaded and/or smooth, to allow the pins **560**, **562** to initially be axially translatable relative to the arms **538**, **540**. The translation allows for adjustability of the height of the system **500** relative to a patient's limb, which may be advantageous if there are tissue swelling, open wounds, and/or skin abrasions on the limb. It is appreciated that the bone pins may be placed in one or any combination of the pin openings **542**.

Referring to FIG. **5**, the first fixation bolt **522** passes through a non-threaded bolt opening **554** in first fixation plate **526**, into the slot **548**, through a bolt opening **544** and out through second slot **550** and a threaded plate bolt opening **555** in second fixation plate **527**. As the threads of bolt **522** engage threaded plate bolt opening **555**, the second fixation plate **527** is drawn toward the first fixation plate **526**, and one or both of fixation plates **527**, **526** may be elastically or plastically deformed. The plate pin openings **552** frictionally bind against pin **562**, preventing it from further axial translation. As the plates **526**, **528** deform they may bow and decrease in length, which pushes the pin **562** against the side wall of the pin bore **542**. This force creates a secondary locking action relative to the pin **562**. The bolt **524** passes through bolt opening **554** in third fixation plate **528**, through a bolt opening **544** and out through second slot **550** and a threaded plate bolt opening **555** in fourth fixation plate **529**. Bolt **524** engages with plates **528**, **529** in the same manner as described for bolt **522** to fix pin **560**. It is appreciated that in other embodiments, other methods of pin capture or fixation known in the art may be used.

Turning to FIGS. **4** and **6**, clamps **534**, **536** are shaped to retain or clamp rod assemblies **506**, **508** while allowing telescoping movement of the rod assemblies to lengthen or shorten the rod assemblies. Clamp **534** has an inner clamping surface **570** which is spherical in the illustrated embodiment; in other embodiments the clamping surfaces may be partially spherical, conical, cylindrical, flat, polygonal, or another shape. In the embodiment shown, the clamps **534**, **536** may be said to hold the corresponding spherical portions **612**, **614** captive because the inner clamping surfaces **570**, **580** are wide enough, parallel to axis **541**, to cover an equatorial diameter, or great diameter, of the corresponding spherical portion **612**, **614** sufficiently to interfere with disassembly at low loads. The inner clamping surface **570** is interrupted by a clamp gap **572** bounded by opposing first and second clamp surfaces **574**, **576**. Similarly, clamp **536** has a spherical inner clamping surface **580**, clamp gap **582**, and first and second clamping surfaces **584**, **586**. In the example shown the inner clamping surfaces **570**, **580** are smooth but in an alternative embodiment they may be ridged or roughened. A bore **590** extends through clamps **534** and **536**, parallel to second axis **535**, intersecting clamp gaps **572**, **582**. Bore **590** also intersects with second slot **550** at the center of the clamp body **520**. The bore **590** includes a first recess **592** at one end and a second recess **594** at the opposite end. A chamber **596** extends lengthwise within the clamp body **520** between the first clamp **534** and the second clamp **536**, and may provide for weight reduction for the clamp body. Clamping bolt **530** extends through bore **590** and engages nut **532**. As the clamping bolt **530** engages the nut **532**, the nut **532** is captured in second recess **594**. Further actuation of bolt **530** draws nut **532** toward the bolt head, engaging recess **594** and closing gaps **572**, **582**. Nut **533**, which may be a wing nut, may also be actuated by hand to tighten bolt **530**. As seen in FIG. **1**, when rod assemblies **506**, **508** are assembled with clamps **534**, **536** as shown and bolt **530** is tightened as described, the rod assemblies are gripped in the clamps and prevented from any movement, for example axial, rotation, or polyaxial, relative to the clamp body **520**. Nut **533** and bolt **530** may include coarse pitch threads for quick tightening.

Referring to FIGS. **7-10**, rod assembly **506** is shown in more detail. Rod assembly **508** may be a mirror image, or may be identical to rod assembly **506** and will not be described further detail. Rod assembly **506** includes an outer or first tubular element **600**, an inner or second tubular element **602**, a locking screw **604** and a rod clamp assembly **606**. The first tubular element **600** has a first end **601** and a second end **603** and shaft **609** extending therebetween; the second tubular element has a first end **605** and a second end **607** and a shaft **619** extending therebetween. The first tubular element **600** is larger in diameter than and coaxially receives a portion of the second tubular element **602**. The tubular members may be circular in cross-section as shown, or in other embodiments may be square, rectangular, triangular, or any other polygonal shape in cross-section. The tubular elements may also be referred to as rods, rod elements, or rod members.

A first tube plug **608** is joined to the first end **601** of first tubular element **600** and a second tube plug **610** is joined to the second end **607** of second tubular element **602**. An inner plug **611** fits inside the first end **605** of the inner tubular element **602**. The tube plugs **608**, **610** have convex spherical portions **612**, **614** which are complementarily shaped to the concave spherical inner clamping surfaces **570**, **580** of the clamps **534**, **536**. First tube plug **608** further includes a neck **613** and an attachment portion **617**, and second tube plug **610** further includes a neck **615** and an attachment portion **619**. The necks **613**, **615** may be smaller in diameter than the respective spherical portions **612**, **614**, and the respective inner and outer tubular elements **600**, **602**. The attachment portions **617**, **619** may be annular and hollow, and sized to be received in the respective tubular elements **600**, **602**. The large and small tube plugs **608**, **610** may be made from machined aluminum. During manufacture they may be assembled to the associated tubes through insertion, bonding, gluing or threading, among other processes.

A line, chain, tether, or other connecting element may extend between inner plug **611** within second tubular element **602** and first tubular element **600**, to prevent inadvertent disconnection between the tubular elements **600**, **602**. As seen in FIG. **9**, a line **629** may be tethered to inner plug **611**, extend through the bore of outer tubular element **600**, and be tethered to a cap **631** received in tube plug **608**. Line **629** may be of sufficient length to allow axial translation between the tubular elements; for example line **629** may be approximately the length of outer tubular element **600**. In other embodiments, other retention features known in the art may be used to prevent disconnection between the first and second tubular elements.

The spherical portions **612**, **614** of the plugs may feature an exterior pattern or texture to enhance the locking strength of the polyaxial clamps. A first pattern may be a negative feature, in which valleys, grooves or slots are cut into the outer surface of the sphere. This is effective where the clamp surface has sufficient compliance to deform elastically or plastically into the negative features. A second pattern may be a positive feature, such as spikes or sharp ridges that extend from the native, or nominal, spherical surface. These positive features are intended to press or cut into the clamp surface in order to create a mechanical interlock between the spherical portion and the clamp. The first pattern may enhance the clamping forces between the two elements without damaging either component. The second pattern may permanently deform one of the two elements, and may be less likely to be reversible. The embodiments disclosed herein may include the first or second patterns, a combination of the two, neither pattern, or another pattern. In other embodiments, texture may be provided by coatings or material deposits. The spherical portions may include openings that serve as drain holes, to permit fluid drainage when a patient bathes.

When assembled with the clamps **534**, **536**, as in FIGS. **1** and **3** for example, the spherical portions **612**, **614** form polyaxially adjustable joints, allowing rotational motion about multiple axes. The polyaxial range of motion of the system **500** is a function of the thickness of the clamps **534**, **536** parallel to axis **541**, the diameter of the spherical portions **612**, **614** of the tube plugs and the diameter of the necks **613**, **615** that connect the spherical portion to the tubular element. The depicted embodiment features +/−30 degrees of motion at each polyaxially adjustable joint. In another embodiment, the range of motion may be +/−45 degrees at each polyaxially adjustable joint. If additional range of motion is required, this can be accomplished by reducing the thickness of the clamps, increasing the diameter of the spherical portions, and/or decreasing the diameter of the neck regions. As the diameter of the neck is reduced, the tube wall thickness may be thicker in order to maintain the same strength. An optimization exercise can be employed to determine the diameter and wall thickness that maximizes both the polyaxial range of motion and the component strength. It is appreciated that the locations of the spherical portions and clamping surfaces can also be reversed to achieve a polyaxial connection between the clamp assembly and a rod assembly. For example, in an embodiment the clamp body **520** may include a convex spherical portion and a rod assembly **506** or **508** may include a concave spherical clamping surface. In another embodiment, spherical portions **612**, **614** may be split spheres which are expanded from within to lock with the spherical clamping surfaces **570**, **580**.

The spherical portions **612**, **614** may have any size diameter according to the intended use of the external fixator embodiment. As the diameter of a spherical portion increases, the clamping force necessary to lock out motion between a spherical portion and its respective spherical clamping surface decreases, and can be reduced to a level that can be locked by finger tightening a wing nut, knob, lever, bolt, or the like. In an embodiment, the diameter of the spherical portion is 0.75 inches or larger. In another embodiment, the diameter of the spherical portion is 1.0 inch or larger. In another embodiment, the diameter of the spherical portion ranges from 1.25 to 1.75 inches. Embodiments with spherical portions of 0.75 inches or larger may be suited to use in the femur, knee, tibia, ankle, and/or foot.

It is appreciated that other embodiments contemplated within the scope of the disclosure include polyaxially adjustable joints at other locations on the systems disclosed herein. In another embodiment, polyaxially adjustable joints may be located at one or more locations along the length of the rod assemblies, instead of or in addition to the polyaxially adjustable joints at the ends of the rod assemblies, for example, they may be formed between first and second rod elements of the rod assemblies. In another embodiment, U-joints allowing rotational movement about two axes may be formed between the rod assemblies and the clamping assemblies. In another embodiment, polyaxially adjustable joints may be formed on the clamping assemblies instead of at the connections between the clamping assemblies and the rod assemblies. In another embodiment, polyaxially adjustable joints may be formed between the bone pins and the clamping bodies. Other embodiments may mix and match the joint locations disclosed herein.

The outer **600** and inner **602** tubes may be specified as standard sized, thin-walled aluminum tubing. They may also be manufactured from carbon fiber reinforced polymer or other materials that provide the desired stiffness and ability to associate with the tube plugs. The shafts **609**, **619** may be smooth to facilitate sliding between them. Indicia **646** may be present on the outsides of the tubular elements to indicate the length of the rod assembly. In some embodiments, grooves may be present on the outside of tubular element **602** to catch binding collar **624** at discrete and/or predetermined positions. In some embodiments, a ratcheting connection may be formed between the first and second tubular elements.

In an embodiment, the rod clamp assembly **606** may be described as a split collar locking device. It may be bonded to the end of the outer tubular element **600** and is oriented to a short slot **616** in that tube. In the example shown in FIG. **8**, the rod clamp assembly **606** includes a locking collar **620**, a pin **622**, a binding collar **624**, a screw **626**, a retention pin **628**, a spring **630** and a retainer **632**. The binding collar **624** is received in an annular recess **621** of the locking collar **620**, and is hinged to the locking collar via pin **622**. A tongue **625** protrudes from the binding collar **624**. The retention pin **628** extends through a bore in the binding collar **624**, through a pin bore **629** in the locking collar, through spring **630** and is captured by retainer **632**. The locking collar **620** further includes a circular bore **660** which is interrupted by a collar gap **662**. A first shoulder **664** and a second shoulder **666** are on opposite sides of the bore gap **662**. Screw **626** is received in a screw bore **627** of the locking collar **620**. The outer tubular element **600** is received in bore **660**, with second end **603** seated against a flange **623**.

The rod clamp assembly **606** further includes a tab member **670**, which is removable to allow the rod clamp assembly **606** to be actuated to provisionally lock the first and second tube members **600**, **602** in a fixed axial or length relationship. Tab member **670** includes a pair of tab extensions **672**. As seen in FIG. **10**, binding collar **624** is received in locking collar **620**. In an unlocked configuration, tab member **670** is attached to the rod clamp assembly **606** with tab extensions **672** are on either side of tongue **625**, captured between the tongue and the shoulders **664**, **666**. The presence of the tab member **670** keeps collar gap **662** open, allowing tubular members **600**, **602** to axially move relative to one another in both directions, by preventing bore **660** from clamping around tubular members **600**, **602** and provisionally locking the tubular members together. In use, tab member **670** may be present on the system **500** when it is removed from packaging, and allows telescoping adjustment of the length of system **500**, in either axial direction, to shorten or lengthen the system **500**.

A provisional, or temporary locking mechanism **650** allows the tubes **600**, **602** to telescope outward, increasing in combined length, but prevents the tubes from collapsing, or decreasing in combined length, unless the lock is released. This type of locking may be described as a one-way motion lock. The rod assembly may be described as being length-stable when the temporary locking mechanism **650** is engaged. The provisional locking mechanism **650** allows for adjustment of the length of the rod assembly before the entire system **500** is locked down into a rigid configuration. This one-way locking mechanism has an unlocked configuration in which the second tubular member can freely translate relative the first tubular member to increase or decrease the length of the external fixation system, and a locked configuration in which the second tubular member can freely translate relative to the first tubular member to increase the combined length of the external fixation system but is prevented from translating relative to the first tubular member to decrease the length of the external fixation system. Removal of the tab member **670** converts the one-way locking mechanism from the unlocked to the locked configuration. Tab member **670** may be tethered to the system **500**, for example via a line, lanyard, split ring, or the like, so that after tab member **670** is disengaged from the rod clamp assembly **606** the tab member **670** is not lost. The tab member **670** may be removed from the rod clamp assembly **606** and reinserted into the rod clamp assembly **606** repeatedly during a medical procedure.

The locking mechanism **650** includes the binding collar **624**, locking collar **620**, retention pin **628**, spring **630** and retainer **632**. After tab member **670** is removed, a closing force is applied by spring **630**, the closing force pushing binding collar **624** against inner tubular element **602**. In this state, tension may be applied to one or both tubular elements **600** and **602** to translate them coaxially apart to increase their combined length; for example, the second clamp assembly **504** may be distracted away from the first clamp assembly **502**. As the elements are pulled apart binding collar **624** and retention pin **628** are advanced toward locking collar **620**, freeing binding collar **624** from engagement with inner tubular element **602**. Once the desired length of the rod assembly **506** is achieved, and the tension is released, the spring force causes binding collar **624** to bind against inner tube **602** provisionally locking the tubes **600**, **602** together and preventing any decrease in their combined length. The closing force is required to ensure that the locking action is automatic and occurs without any backlash. In the context of this disclosure, automatic locking refers to locking that does not require any additional action by the user to accomplish the locking; once the pulling force ceases allowing binding collar **624** to bind against inner tube **602**, the length of rod assembly **506** is locked without any further steps. It is appreciated that provisional locking mechanism **650** allows locking of the two tubular elements together anywhere along a continuum on the outer surface of inner tubular element **602**. In other words, the provisional locking mechanism **650** allows locking of the two tubular elements together at any one of an infinite number of locations along the other surface of the inner tubular element. During system lengthening, binding collar **624** may be parallel with locking collar **620**; during provisional locking, binding collar **624** may be angled relative to locking collar **620** as it binds against the inner tubular element.

After provisional locking, further locking of each rod assembly may be accomplished by turning screw **626**. As screw **626** is tightened, the inner diameter of the locking collar **620** decreases and compresses over the rod slot **616**, reducing the effective inside diameter of the large tube **600** until it compresses around the outside of the small tube **602**. Screw **626** and plug **611** may include coarse pitch threads for quick tightening.

Locking screw **604** may also be tightened to more permanently fix the length of rod assembly **506**, and/or to increase the rigidity of the rod assembly **506**. The locking screw **604** and inner plug **611** act to remove any backlash or looseness that may exist between the outer diameter of the first end **605** of the small tube **602** and the inner diameter of the large tube **600**. The locking screw **604** includes a screw head **634** and a shaft **636** with a threaded portion **638**. The inner plug **611** includes a protrusion **642** and a threaded bore **644**. As screw **604** is rotated, the threaded portion **638** of the screw engages the threaded bore **644** of the inner plug **611** and protrusion **642** indexes into one of the slots **640** in the tube to prevent the plug from spinning as the screw **604** turns. Protrusion **642** may be referred to as a key and slot **640** may be referred to as a keyway. The first end **605** of the inner tube **602** features several slots **640** that allow the tube to expand as the tapered inner plug **611** is drawn into it by rotation of the screw **604**. Screw **604** may be turned until inner tubular member **602** has expanded sufficiently to cause first end **605** of inner tubular member **602** to fit tightly within outer tubular member **600**, and lock its position relative to outer tubular member **600**. The screw head **634** protrudes from the small tube plug **610** and is therefore readily accessible yet largely out of the way.

It is appreciated that other locking assemblies known in the art may be used to clamp the tubular portions together and fix the length of a rod assembly. In an embodiment, a two piece compression lock may be used to fix the length of a rod assembly. The outer tubular element may be rotated about the inner tubular element to compress about the inner tubular element and lock the length of the rod assembly. In another embodiment, a wedge member may be substituted for inner plug **611** to expand inner tubular element **602** within outer tubular element **604** and lock the tubular elements together. In another embodiment, hydraulic expansion may be used to lock the tubular elements together at a desired length. In another embodiment, a dovetail and tab system may be used to lock the tubular elements together at a desired length. In another embodiment, a ball and ramp frictional lock may be used to lock the tubular elements together.

In an embodiment, external fixation system **500** is available in a kit **700**, as shown in FIG. **11**. Kit **700** may include a tray **702**, the pre-assembled external fixation system **500**, a plurality of bone pins **510**, **560** and/or **562**, a drill guide **704**, drill sleeves **706**, and/or a wrench **708**. The kit may be sterile packaged in the peel-pack tray **702**, which may be sealed.

In a method of use, kit **700** is opened and the drill guide **704** removed. The drill guide **704** is positioned at a first bone portion on the patient, drill sleeves **706** are inserted into the drill guide, and passages are drilled through drill sleeves and guide, through the adjacent tissues, and into the bone portion. The drill sleeves may prevent soft tissue from wrapping around the drill and/or pin during this step. One or more of the bone pins **560**, **562** are inserted through the drilled passages and fixed in the first bone portion. In an alternative embodiment, the pins may be placed without the use of the drill guide and drill sleeves; in one alternative, the system **500** may be removed from the kit and positioned so that the first and second clamping assemblies **502**, **504** are on opposite sides of the fracture, joint, or other discontinuity, and the pins may be placed through the first clamping assembly **502**.

The system **500** is removed from the kit and positioned so that the first clamping assembly **502** is placed over the one or more bone pins **560**, **562** with each bone pin **560** and/or **562** received in a pin bore **542**. The fixation bolts **522**, **524** are tightened to fix the clamping body **520** to the bone pin(s). The system **500** may be lengthened or shortened by axially translating outer tubular members **600** relative to the inner tubular members **602**. The length of system **500** is adjusted to span the joint and/or fracture. To adjust the system length, the second clamping assembly **504** may be pulled axially toward or away from the first clamping assembly **502** to lengthen or shorten the assembly. When the desired length is achieved, the second clamping assembly **504** may then be used as a drill guide for one or more additional bone pins **560**, **562** to be fixed in the second bone portion. The additional bone pin(s) may be placed in the second bone portion out of plane from the bone pin(s) in the first bone portion. After at least one additional bone pin is placed in the second bone portion, the second clamping assembly is mounted on the additional bone pin(s), and the fixation bolts **522**, **524** of the second clamping assembly **504** are tightened to fix the second clamping body **520** to the additional bone pin(s) in the second bone portion. It is noted that the polyaxial connections allow the system **500** to twist sufficiently to allow the clamping assemblies **502**, **504** mount to first and second sets of bone pins, respectively, which are out of plane from one another. The tab members **670** are removed. The system **500** is lengthened to provide traction, reduce the fracture and establish the proper limb length between the first and second bone portions, the inner tubular elements **602** non-rotatably sliding relative to the outer tube elements **600**. The system **500** can be lengthened generally parallel to axis **541**, within the polyaxial range of motion, by grasping and pulling clamping assembly **502** axially away from clamping assembly **504**. Alternatively, the practitioner may grasp the patient's limb, at the foot for example, and pull axially to lengthen the limb and the system **500**. When lengthening ceases, the system **500** automatically provisionally locks in a one-way manner as described above, with binding collars **624** engaged against inner tubular elements **602**, in what may be referred to as primary locking. The provisional locking may occur when the clamping assembly **502** is released from the tension of pulling. In this arrangement, the practitioner may apply distraction forces intermittently, and may rely upon the one-way lock to maintain a length-stable construct during periods of no distraction force. This may be advantageous to the practitioner, as rest periods may be taken without sacrificing reduction. The rest periods may also permit reassessment of reduction quality, or they may allow gradual atraumatic stretching of swollen, cramped, or spasming muscles or other soft tissues. The system facilitates obtaining an initial reduction followed by an iterative process of refining the reduction without the stress and fatigue associated with constantly maintaining traction on the limb. For example, the reduction may be refined by rotating one bone portion relative to the other bone portion.

After provisional locking at the desired length, at least one of the screws **626** may be tightened to lock the locking collar **620** around the rod assembly, in what may be referred to as secondary locking by activating a second locking mechanism. The limb or bone portions may be further manipulated to achieve proper segment alignment; the spherical portions **612**, **614** may polyaxially rotate within their respective inner clamping surfaces **570**, **580**. For example, one or both of the bone portions may be rotated while the system **500** automatically maintains the desired length. Once the desired bone alignment is achieved, the clamping bolts **530** on each clamp assembly **502**, **504** are tightened to lock the clamping assemblies **502**, **504** to the rod assemblies **506**, **508** with the clamping surfaces **570**, **580** compressing around the spherical portions **612**, **614** to prevent further polyaxial motion. Wing nuts **533** may be finger tightened to tighten the clamping bolts **530**. The remaining screw **626** may also be tightened at this time, if loose. The locking screws **604** in each rod assembly **506**, **508** are tightened to further lock the relative position of the telescoping inner and outer tubular elements **600**, **602**, in what may be referred to as tertiary locking by activating a third locking mechanism. During the procedure, wrench **708** may be used to adjust the screws and bolts of the assembly **500**.

The one-piece assembly **500** and one-way automatic locking of the rod assemblies **506**, **508** can be advantageous when quick, secure setting of a patient's limb or joint is desired. In contrast with external fixation systems which require assembly of separate rods, clamps and other structures during the external fixation procedure, system **500** is pre-assembled and packaged as one piece which is easily manipulated in a user's two hands. After mounting to the bone pins, system **500** is easily telescopically lengthened by pulling one clamping assembly **502** away from the other clamping assembly **504**; when the clamping assembly is released the automatic one-way locking mechanism prevents collapse or shortening of the assembly **500**. The one-way provisional locking mechanism maintains the length of the assembly **500** while final adjustments are made and the secondary locking mechanisms are deployed.

The system **500** provides single point tightening and loosening at each one of the locking mechanisms. Length can be locked progressively, or unlocked and adjusted, without unlocking the clamps, and vice versa.

For ease of use, indicia or labeling may be provided on locking screws or other parts. In one non-limiting example, fixation bolts **522**, **524** are each marked with a '1' to indicate that they should be actuated first. Similarly, clamping bolts **530** may be marked with a '2'; screws **626** may be marked with a '3', and locking screws **604** may be marked with a '4' to indicate the proper order of actuation and locking. In other embodiments, locking may occur in a different order and the screws or parts may be labeled accordingly.

The clamping bodies **520**, locking collars **622** and binding collars **624** may be injection molded in plastic, preferably in a fiber reinforced material to resist creep under a prolonged load. For example fiber-filled PEEK (polyetheretherketone) may be used, and may incorporate glass or carbon fibers. In another embodiment, the clamping bodies are made from machined aluminum. The pins, bolts, screws, nuts and springs may be made of stainless steel or a stainless alloy, preferably non-magnetic. The fixation plates **526-529** and binding collar **624** may be made of stainless steel or other metal, preferably non-magnetic. The locking collar **622**, and inner and outer tubular elements **602**, **600** may be formed of aluminum. The spherical portions **612**, **614** may be cast, may be machined from aluminum, or may be molded from PEEK. Inner plug **611** may be injection molded in plastic, or in other embodiments may include aluminum or fiber-filled PEEK. Some or all parts may be radiolucent. It is appreciated that system **500** may be provided in various sizes and/or lengths so that a practitioner can select a system suited to the size or needs of the patient. For example, longer or shorter rod assemblies may be used to build systems with longer or shorter overall lengths. Rods of various diameters may also be available to scale the external fixation system to the intended use. It is also appreciated that in an embodiment, only one rod assembly may be included in the system. In another embodiment, more than two rod assemblies may be included in the system, with an appropriate number of clamps for clamping the rod assemblies.

Another embodiment includes an external fixation system **800** which may be referred to as an ankle spanning system **800** or joint spanning system, although external fixation system **800** may also be used to span a fracture, osteotomy, epiphyseal plate, or other discontinuity between bone portions. Referring to FIGS. **12-18**B, external fixation system **800** includes the first clamping assembly **502**, the first rod assembly **506** and the second rod assembly **508**, and a clamping subassembly **802**.

The clamping subassembly **802**, which may be referred to as an ankle clamping subassembly, can connect to and extend between the first and second rod assemblies **506**, **508**, and includes a first clamping strut assembly **804**, a second clamping strut assembly **806**, a spanning member **808**, and a pin clamp assembly **810**. Two calcaneal pins **812**, **814** extend between the first and second clamping strut assemblies **804**, **806**; each calcaneal pin includes a threaded portion **815**. The first clamping assembly **502**, first rod assembly **506** and second rod assembly **508** are as described above with reference to FIGS. **1-10**; in this embodiment the rod assemblies may be shorter than those depicted in FIGS. **1-10**. The external fixation system **800** can provide rigid fixation of the ankle joint, to stabilize the foot and ankle with respect to the tibia, for example in the case of a lower tibial fracture or an injured ankle joint.

Referring to FIGS. **14-16**, the first and second clamping strut assemblies **804**, **806** may be mirror images, or may be identical to one another except for the direction in which locking bolts, screws, or pins are inserted; thus the description of first clamping strut assembly **804** also applies to assembly **806**. First clamping strut assembly **804** includes a clamping strut **820**, first and second fixation plates **822**, **824**, spacing member **826**, first fixation bolt **828**, second fixation bolt **830**, nut **832**, a fixation member **834** and two dowel pins **836**. The clamping strut **820** includes a strut portion **840**, a split clamp portion **842**, and a pin clamp portion **844**. From a side view, the clamping strut may be generally Y-shaped. The strut portion **840** may be straight, and oval in cross section, although other cross-section shapes such as circular, square or rectangular are contemplated within the scope of the disclosure. The strut portion **840** includes a fixation member bore **841** and may include additional bores to receive dowel pins, to enable connection to the spanning member **808**. At least one of the bores in the strut portion may be threaded. In an embodiment, fixation plates **822**, **824** are structurally the same as fixation plates **526-529**. Each fixation plate **822**, **824** includes a bolt opening **870** and several pin openings **872**. Bolt and pin openings **870**, **872** may be threaded or non-threaded. It is noted that the threaded portion **815** on each calcaneal pin may be smaller diameter than threading in the pin openings **872** on the fixation plates, allowing the calcaneal pins to be freely inserted through the fixation plates.

The split clamp portion **842** of the clamping strut **820** includes first and second clamp arms **850**, **852** which face one another and encircle a spherical clamping surface **854**, which is interrupted by a gap **856**. A fixation bore **858** extends through a distal end of the split clamp portion **842**, and is interrupted by the gap **856**. When operatively assembled as in FIG. **14**, the spherical portion **612** of rod assembly **506** is received within the clamp arms **850**, **852** and encircled by the spherical clamping surface **854** so that the spherical portion **612** is captive within the clamp arms **850**, **852**. The rod assembly **506** may be polyaxially adjustable within the split clamp portion **842** until a desired position is reached. Second fixation bolt **830** may be actuated to draw the first and second clamp arms **850**, **852** together, closing the gap **856** and locking the position of the rod assembly **506** relative to the clamping strut **820**.

The pin clamp portion **844** includes a first support arm **860** having a first recess **862**, opposite a second support arm **864** having a second recess **866**, each recess shaped to receive a fixation plate **822**, **824**. The support arms **860**, **864** are separated by an arm gap **868**. When operatively assembled as in FIG. **14**, the first fixation plate **822** is received in first recess **862**, second fixation plate **824** is received in second recess **866**, and spacing member **826** is received between the support arms **860**, **864** in the arm gap **868**. First fixation bolt **828** extends through bolt opening **870** the first fixation plate **822**, through the spacer member **826** and into the bolt opening **870** in second fixation plate **824**. Calcaneal pins **812**, **814** extend transversely through pin openings **872** in the fixation plates, through the support arms

860, **864**, and through the arm gap **868**. When fixation bolt **828** is tightened, threads on the fixation bolt **828** may engage threads in the bolt opening **870** on the second fixation plate **824** so that tightening the bolt draws the first and second fixation plates toward one another and one or both of fixation plates **822**, **824** may be deformed. The pin openings **872** frictionally bind against calcaneal pins **812**, **814** preventing them from further axial translation relative to the clamping strut assembly **804**. It is appreciated that in other embodiments, other methods of pin capture or fixation known in the art may be used.

Referring to FIGS. **17**A-**17**C, spanning member **808** includes first and second attachment sections **880**, **882** which are bridged by a span section **884**. In the embodiment shown span section **884** is curved to fit over a patient's appendage. The size, shape and curvature of the spanning member **808** may be varied to accommodate variations in patient size or appendage configuration; in some embodiments the spanning member may be straight. Each attachment section includes a first bore **886** and one or more secondary bores **890**. On an outer side of the member **880**, a recess **888** surrounds the first bore **886**. As seen in FIGS. **14** and **16**, spanning member **808** may be operatively attached to each clamping strut assembly **804**, **806**. Dowel pins **836** are received in openings on the clamping struts **820** and in the secondary bores **890** in the spanning member. Fixation member **834** extends through first bore **886** and into bore **841** on the clamping strut **820** to secure the spanning member **808** to the clamping strut **820**. A head portion of the fixation member **834** is received in the recess **888** to provide a low profile to the assembly.

It is appreciated that variations in the configuration of the clamping strut assemblies **804**, **806** and the spanning member **808** may occur. For example, in another embodiment the strut portions may be shorter than those depicted, and the attachment sections **880**, **882** may extend toward the strut portions. In another embodiment, a separate spanning member may not be present; instead the spanning member may be integrally formed with the clamping strut assemblies to bridge between them. In another embodiment, the spanning member may be absent; the calcaneal pins may form the connection between the clamping strut assemblies.

Referring to FIGS. **18**A and **18**B, pin clamp assembly **810** includes a clamp body **900** having a pin clamp portion **902** and a spanning member clamp portion **904**. The clamp portions **902**, **904** may be angled relative to one another. The pin clamp portion **902** includes first and second spherical openings **906**, **908**. A slot **910** intersects both spherical openings. A first split sphere **912** is received in the first spherical opening **906** and a second split sphere **914** is received in the second spherical opening **908**. A first fixation pin **916** is received through the first split sphere **912** and a second fixation pin **918** is received in the second split sphere **914**. The split spheres are polyaxially adjustable within the spherical openings, allowing the trajectories of fixation pins to be adjusted to connect with targeted bone portions, such as a metatarsal bone, or other structures. A first bolt opening **920** extends through the pin clamp portion **902** transverse to the spherical openings, and receives a first clamping bolt **922**. When clamping bolt **922** is tightened, the width of slot **910** decreases and the spherical openings **906**, **908** are compressed around the spherical members **912**, **914**, locking the positions of the spherical members and the captured pins **916**, **918**.

Spanning member clamp portion **904** includes a member opening **928** surrounded by a member clamping surface **930**. Both the member opening **928** and clamping surface **930** are interrupted by a member clamping gap **932**. A second bolt opening **934** extends through clamp portion **904** and a second clamping bolt **936** extends through the bolt opening **934**, bridging the gap **932**. When operatively assembled as in FIG. **12**, for example, spanning member **808** is received in the member opening **928**, and the pin clamp assembly **810** may be translated along the spanning member **808** until a desired or targeted position is reached. Second clamping bolt **936** is actuated to close the gap **932** and compress clamping surface **930** around the spanning member **808**, preventing any further translation of the pin clamp assembly **810** relative to the spanning member **808**.

In an embodiment, external fixation system **800** is available in a kit. The kit may include a tray, the pre-assembled external fixation system **800**, a plurality of bone pins **560**, **562**, **916**, **918**, calcaneal pins **812**, **814**, a drill guide **704**, drill sleeves **706**, and/or a wrench **708**. The kit may be sterile packaged in the tray.

In a method of use of system **800** to immobilize an ankle joint, one or more of the following steps may be present. The tray is opened and the system **800** is removed from the tray. With reference to FIG. **12**, the first bone pin **560** is placed in the tibia. The pre-assembled system **800** with clamping assembly **502** is placed over the first bone pin **560**, with pin **560** extending through a pin opening **542** in clamp body **520**. The spanning member **808** is rested over the foot, with the first and second clamping strut assemblies **804**, **806** along either side of the foot in a generally aligned position. Using the clamping assembly **502** as a guide, the second tibial pin is extended through another pin opening **542** in clamp body **520** and into the tibia. The clamping assembly **502** is locked to the bone pins **560**, **562** by tightening fixation bolts **522**, **524**. The first and second clamping strut assemblies **804**, **806** are aligned to the calcaneus and one of the first or second calcaneal pins **812**, **814** is driven through first and second clamping strut assemblies **804**, **806** as well as the bone. The polyaxial alignment of the rod assemblies **506**, **508** is adjusted relative to the clamping assemblies **502**, **804** and **806**. The polyaxial clamps are provisionally locked by tightening clamping bolt **530** in clamping assembly **502**, and by tightening fixation bolts **830** in clamping strut assemblies **804**, **806**. The pin clamp assembly **89** is slid along the spanning member **808** until it provides the proper approach angle to the great toe metatarsal. The position of the pin clamp assembly **810** on the spanning member is locked by tightening clamping bolt **936** in the spanning member clamp portion **904**. One or both metatarsal pins **916**, **918** are placed through the polyaxial split spheres **912**, **914** and into the metatarsal. The pins **916**, **918** are locked into the pin clamp portion **902** by tightening clamping bolt **922**.

The other of the first and second calcaneal pins **812**, **814** is inserted through the first and second clamping strut assemblies **804**, **806** as well as the bone. The calcaneal pins **812**, **814** are locked into the first and second clamping strut assemblies **804**, **806** by tightening fixation bolts **828** to frictionally lock the pins to the clamping struts **820**. The tab members **670** are removed from the rod assemblies **506**, **508**. If required, the limb is placed in traction to re-establish the proper limb length. When the traction is released, the one-way provisional locking of the rod assemblies as described previously will maintain the established length. Binding collar **624** engages against inner tube **602** to prevent telescopic collapsing, or a decrease in the length of the rod assembly. The limb position may be adjusted as necessary, which may include loosening polyaxial clamping bolts **530**, **830**, adjusting the relative position of the rod assemblies and re-tightening the polyaxial clamping bolts **530**, **830**. Screws

626 on locking collars **620** are tightened to prevent axial translation of the inner and outer tubes **602**, **600** relative to one another. Locking screws **604** are tightened to expand each inner tube member **602** and lock its position relative to outer tube member **600**.

Referring to FIGS. **19** and **20**, an external fixation system **1000** is a two-level system which includes system **500**, which may span a knee joint, and system **800**, which may span an ankle joint. Both systems **500**, **800** are mounted on a common set of bone pins **560**, **562** which may be mounted in a tibia. System **1000** may provide rigid fixation of the both the knee and ankle joints. Systems **500** and **800** may be vertically stacked on one set of pins without further modification as shown in FIGS. **19** and **20**. In another embodiment, the clamp bodies **520** may be modified to allow systems **500** and **800** to be mounted horizontally relative to one another, for example adjacent to one another along second axis **535**.

In a method of use of external fixation system **1000**, bone pin **560** is mounted in a tibia. External fixation system **800** is mounted on bone pin **560** and as described previously, through the step of the one-way provisionally locking of the rod assemblies. After external fixation system **800** is mounted and provisionally locked, external fixation system **500** is mounted on to bone pins **560**, **562** and the rod assemblies are provisionally locked as described previously for system **500**. After the provisional locking of systems **500** and **800**, final limb adjustments and locking steps for both systems can be iteratively carried out as needed. It will be appreciated that additional systems **500** and/or **800** may be mounted sequentially to extend the zone of fixation as far as necessary.

Another embodiment includes an external fixation system **1100** which may be referred to as a wrist spanning system **1100** or joint spanning system, although external fixation system **1100** may also be used to span a fracture, osteotomy, epiphyseal plate, or other discontinuity between bone portions. Referring to FIGS. **21-27**, external fixation system **1100** includes a first clamping assembly **1102**, a second clamping assembly **1104**, and the first rod assembly **506**. The rod assembly **506** extends between and connects the clamping assemblies **1102**, **1104** into the single system **1100**. The rod assembly **506** may be scaled in length and/or diameter to an appropriate size for the wrist. The clamping assemblies may be referred to as support elements or members, as they support the rod assembly. The first and second clamping assemblies may be mirror images, or may be identical to one another. As described above, using identical assemblies in a system may enable the entire system to be produced more cheaply and/or quickly than a system in which each separate component or assembly is unique.

In use, system **1100** can be secured to the patient in one piece, as a unit. First clamping assembly **1102** may be fixed to a first bone portion by one or more fixation pins **510**. Bone screws, bone pins, wires, and/or other fasteners may be used in place of or in combination with fixation pins **510**. Second clamping assembly **1104** may be fixed to a second bone portion by additional fixation pin(s) **510**. The rod assembly **506**, extending between the clamping assemblies, may span a joint or fracture between the first and second bone portions. After the clamping assemblies **1102**, **1104** are fixed to the bone portions, the rod assembly **506** may be lengthened or shortened to a desired length and provisionally locked to stabilize the joint or fracture. Following the provisional locking, the polyaxial connections of the assembly may be adjusted, then more permanently locked.

Referring to FIGS. **22-26**, clamping assembly **1102** is shown in more detail. Clamping assembly **1104** may be a mirror image, or may be identical to clamping assembly **1102** and will not be described in further detail; the description of clamping assembly **1102** also applies to clamping assembly **1104**. Clamping assembly **1102** includes a clamp body **1120** which is formed as a single piece. Clamping assembly **1102** further includes first fixation bolt **1122**; first and second fixation plates **1126**, **1127**; a clamping bolt **1130**; first nut **1132**; and second nut **1133**. The fixation plates may be referred to as locking plates. The rod assembly **506** is polyaxially adjustably connected to the clamping assembly **1102** via a clamp **1134** which is formed as part of the clamping body **1120**. Two bone pins **560**, **562** extend through the clamping body **1120** to fix the clamping assembly **1102** to a bone portion. In another embodiment, only one bone pin may be used in each clamping assembly.

Referring to FIGS. **21-26**, clamp body **1120** may be T-shaped and includes an upper or first surface **1112** and a lower or second surface **1114** opposite the first surface. The clamp body **1120** further includes a first arm **1138** and a second arm **1140** which extend along a first axis **1141**, perpendicular to the first clamp **1134**, which extends along a second axis **1135**. First axis **1141** may be parallel to the longitudinal lengths of rod assembly **506** when the system **1100** is in a neutral or orthogonal arrangement. A bolt opening **1144** extends through the clamping body **1120** in the same direction as the pin openings **1142**, **1152** described below. In the example shown, the bolt and pin openings extend in a direction perpendicular to the first axis **1141** and the second axis **1135**. A first slot **1148** is recessed into the first surface **1112**, and a second slot **1150** is recessed into the second surface **1114**, opposite the first slot. The first and second slots are elongated, occupying the majority of the length of the first and second arms **1138**, **1140**, and the slots are parallel with first axis **1141**. A plurality of pin openings or bores **1142** extend through the arms between the first and second slots **1148**, **1150**, each pin bore sized to receive a bone pin **510**. First fixation plate **1126** is housed in the first slot **1148** and second fixation plate **1127** is housed in the second slot **1150**. Each fixation plate **1126**, **1127** includes at least one plate pin opening **1152**, and one of a threaded plate bolt opening **1154** or a non-threaded plate bolt opening **1155**. Each fixation plate **1126**, **1127** is elongated, having a first extension **1156** and a second extension **1158**.

The bone pins **560**, **562** are received in pin openings **1142** of clamp body **1120**. Each bone pin may pass through a plate pin opening **1152** in a fixation plate, through the first slot **1148**, through a pin bore **1142**, through the second slot **1150**, and out through a plate pin opening **1152** in another fixation plate. The opening for the pins may be non-threaded and/or smooth, to allow the pins **560**, **562** to initially be axially translatable relative to the arms **1138**, **1140**. The translation allows for adjustability of the height of the system **1100** relative to a patient's limb, which may be advantageous if there is tissue swelling, an open wound, and/or a skin abrasion on the limb. It is appreciated that the bone pins may be placed in one or any combination of the pin openings **1142**.

Referring to FIG. **25**, the first fixation bolt **1122** passes through a non-threaded bolt opening **1155** in first fixation plate **1126**, into the first slot **1148**, through a bolt opening **1144** and out through second slot **1150** and a threaded plate bolt opening **1154** in second fixation plate **1127**. As the threads of bolt **1122** engage threaded plate bolt opening **1154**, the center portion of second fixation plate **1127** is drawn toward the center portion of first fixation plate **1126** against the resistance of first and second extensions **1156**, **1157** bearing in slots **1148**, **1150**, causing one or both of fixation plates **1127**, **1126** to be elastically or plastically deformed. As a result of the elastic or plastic deformation, the plate pin openings **1152** frictionally bind against pin **562**, preventing pin **562** from further axial translation relative to the clamp body **1120**. As the plates **1126**, **1128** deform, they may bow and decrease in length, which pushes the pin **562** against the side wall of the pin bore **1142**. This force creates a secondary locking action relative to the pin **562**. It is appreciated that in other embodiments, other methods of pin capture or fixation known in the art may be used.

Turning to FIGS. **23-24** and **26**, the clamp **1134** is shaped to retain or clamp rod assembly **506** while allowing telescoping movement of the rod assembly to lengthen or shorten the rod assembly. Clamp **1134** has an inner clamping surface **1170** which is spherical in the illustrated embodiment; in other embodiments the clamping surfaces may be partially spherical, conical, cylindrical, flat, polygonal, or another shape. The inner clamping surface **1170** is interrupted by a clamp gap **1172** bounded by opposing first and second clamp surfaces **1174**, **1176**. In the example shown the inner clamping surface **1170** is smooth, but in an alternative embodiment it may be ridged or roughened. A bore **1190** extends through the clamp **1134**, parallel to second axis **1135**, intersecting clamp gap **1172**. The bore **1190** includes a first recess **1192** at one end and a second recess **1194** at the opposite end. One or more chambers **1196** extend into the clamp body **1120** between the pin openings **1142**, and may provide for weight reduction for the clamp body. Clamping bolt **1130** extends through bore **1190** and engages nut **1132**. As the clamping bolt **1130** engages the nut **1132**, the nut **1132** is captured in second recess **1194**. Further actuation of bolt **1130** draws nut **1132** toward the bolt head, engaging recess **1194** and closing gap **1172**. Nut **1133**, which may be a wing nut, may also be actuated to tighten bolt **1130**. As seen in FIG. **21**, when rod assembly **506** is assembled with clamp assemblies **1102**, **1104** as shown and bolt **1130** is tightened as described, the rod assembly is gripped in the clamps **1134** and prevented from any movement, for example axial, rotation, or polyaxial, relative to the clamp body **1120**.

In an embodiment, external fixation system **1100** is available in a kit, similar to that shown in FIG. **11**. The kit for external fixation system **1100** may include a tray, the preassembled external fixation system **1100**, a plurality of bone pins **560** and **562**, a drill guide **704**, drill sleeves **706**, and/or a wrench **708**. The kit may be sterile packaged in a peel-pack tray, which may be sealed.

A method of use of external fixation system **1100** may be similar to, or identical to, that described above for external fixation system **500**.

FIG. **28** is a perspective view of another clamping assembly, including two bone pins. The clamping assembly **1200** of FIG. **28** can include a main clamp body **1202**, a first clamp **1204** having an inner surface **1206** for connecting to a first rod assembly, e.g., rod assembly **506** of FIG. **1**, a second clamp **1208** having an inner surface **1210** for connecting to a second rod assembly, e.g., rod assembly **508** of FIG. **2**, and two bone pins **1212**, **1214**.

In contrast to the clamping assembly **502** of FIGS. **3-5** in which two bolts, namely the first and second fixation bolts **522**, **524**, lock the bone pins **560**, **562** (described in detail above), the clamping assembly **1200** in FIG. **28** includes a single fixation bolt **1216** that can lock one or more bone pins simultaneously, e.g., both bone pins **1212**, **1214** simultaneously. In addition, instead of actuating from a direction substantially parallel to the bone pins **560**, **562** like in FIGS. **3-5**, the single fixation bolt **1216** of the clamping assembly **1200** of FIG. **28** can actuate from a direction substantially perpendicular to the bone pins **1212**, **1214**, e.g., along a longitudinal axis of the main clamp body. For example, as seen in FIG. **28**, the fixation bolt **1216**, e.g., a bolt or screw, can extend into and actuate from the side of the main clamp body **1202**. As shown and described below in FIGS. **29** and **30**, the clamping assembly **1200** can include a sliding clamp **1218** that can lock the bone pins **1212**, **1214** against the main clamp body **1202** or any installed bushings.

FIG. **29** is a top view of a portion of the main clamp body **1202** depicted in FIG. **28**, depicting the sliding clamp **1218** in an open position. In FIG. **29**, as the sliding clamp **1218** is moved toward the right by tightening the fixation bolt **1216**, the sliding clamp **1218** can lock the bone pins **1212**, **1214** of FIG. **28** against the main clamp body **1202**.

To help align and prevent the sliding clamp **1218** from rotating within the main clamp body **1202**, the clamping assembly **1200** can include a sliding clamp pin **1220**. In addition, two pins **1222**A, **1222**B can help retain and/or align the fixation bolt **1216** within the main clamp body **1202**. The sliding clamp **1218** is shown in detail in FIG. **33**.

The main clamp body **1202** can define a plurality of holes **1224**A-**1224**D, through which the bone pins **1212**, **1214** can be inserted. In some example configurations, the holes **1224**A-**1224**D can be sized to accommodate the use of tissue sleeves disposed over the bone pins **1212**, **1214** (as seen in FIG. **32**).

In some example configurations, the main clamp body **1202** can include one or more bushings, e.g., bushings **1226**A-**1226**D (referred to collectively as "bushings **1226**" and shown in FIG. **29**). The bushings **1226** can be used instead of the fixation (or locking) plates **526**, **528** of FIG. **3**.

FIG. **30** is a top cross-sectional view of the portion of the main clamp body **1202** depicted in FIG. **29**, depicting the sliding clamp **1218** in an open position. As seen in FIG. **30**, the sliding clamp **1218** defines two apertures **1228**A, **1228**B (referred to collectively as "apertures **1228**"). The apertures **1228** can be at least partially defined by ramps **1230**A-**1230**D (referred to collectively as "ramps **1230**"). In this disclosure, the ramps **1230** can be defined as having a slope relative to an axis extending along the length of the sliding clamp **1218**. In some example configurations, the ramps **1230** can include curved portions and/or straight portions. The ramps **1230** of the sliding clamp **1218** can provide a clamping force that can lock the bone pins **1212**, **1214** against the main clamp body **1202** (or against any bushings **1226**, if installed). As seen in FIG. **30**, when the sliding clamp **1218** is pulled toward the right via the fixation bolt **1216**, the ramps **1230** can slide along the bone pins **1212**, **1214** and gradually secure the bone pins to the main clamp body **1202** as the dimensions of the apertures **1228** decrease. The sliding clamp pin **1220** can help the sliding clamp **1218** move laterally as the fixation bolt **1216** pulls the sliding clamp **1218** toward the right in FIG. **30**.

In addition, the design of the main clamp body **1202** of FIG. **29** can permit the use of tissue sleeves **1232**, **1234** (shown in FIG. **33**) over the bone pins **1212**, **1214**.

In some alternative configurations, the interference can be a wall of the apertures, and does not need to be a ramp.

FIG. **31** is a top view of a portion of the main clamp body depicted in FIG. **28**, depicting the sliding clamp **1218** in a closed position. The fixation bolt **1216** has pulled the sliding clamp **1218** into a closed position. As seen in FIG. **31**, the ramp **1230**A and the ramp **1230**D have reduced the through-hole size, thus creating a clamping force between the sliding clamp **1218** and the main clamp body/bushing at each hole location. The associated bone pins **1212**, **1214** can flex or bend to allow a lock to occur at each position.

FIG. **32** is a cross-sectional view of an example portion of the main clamp body **1202** of FIG. **29**. A tissue sleeve **1232** can extend through the main clamp body **1202** and the sliding clamp **1218**. In the example of FIG. **32**, bushings **1226**A, **1226**E are coaxially positioned within a hole defined by the main clamp body, e.g., hole **1224**A of FIG. **29**.

FIG. **33** is a cross-sectional view of the clamping assembly **1200** of FIG. **28**. The sliding clamp **1218** is shown in an open position. As the fixation bolt **1216** pulls the sliding clamp **1218** to the right in FIG. **33**, the sliding clamp **1218** can secure the bone pins, e.g., bone pins **1212**, **1214** of FIG. **28**, against the main clamp body **1202**. The holes **1224**A, **1224**D are sized to accommodate the use of tissue sleeves **1232**, **1234**.

As described above with respect to FIG. **30**, the ramps **1230**A-**1230**D of the sliding clamp **1218** can provide a clamping force that can lock the bone pins **1212**, **1214** against the main clamp body **1202** (or against any bushings **1226**, if installed). FIGS. **34**-**37** depict various examples of alternative sliding clamp configurations that may be used with the main clamp body **1202**.

FIGS. **34**A and **34**B depict another example of a sliding clamp that can be used in accordance with various techniques of this disclosure. FIG. **34**B depicts an enlarged area of the example sliding clamp **1218** of FIG. **34**A. For purposes of conciseness, FIGS. **34**A and **34**B will be described together.

The sliding clamp **1218** of FIGS. **34**A and **34**B can include one or more ramps **1230**A-**1230**D having portions that define a plurality of teeth **1236**. The teeth **1236** can improve the torsional rotation resistance of the bone pins on the sliding clamp **1218**. As seen in FIG. **34**B, a first portion of a ramp, e.g., ramp **1230**B, can define teeth **1236** while a second portion **1238** of the ramp remains substantially smooth. In addition, a straight portion **1240** of the sliding clamp **1218** adjacent to the teeth **1236** of the first portion of the ramp, e.g., ramp **1230**B can also define the teeth **1240**. As the fixation bolt **1216** (FIG. **30**) pulls the sliding clamp **1218** laterally, the teeth **1236** can grip a bone pin thereby increasing the locking force.

FIGS. **35**A and **35**B depict another example of a sliding clamp that can be used in accordance with various techniques of this disclosure. FIG. **35**B depicts an enlarged area of the example sliding clamp **1218** of FIG. **35**A. For purposes of conciseness, FIGS. **35**A and **35**B will be described together.

Like the sliding clamp shown in FIGS. **34**A and **34**B, the sliding clamp **1218** of FIGS. **35**A and **35**B can include one or more ramps **1230**A-**1230**D having portions that define a plurality of teeth **1236**. The teeth **1236** can improve the torsional rotation resistance of the bone pins on the sliding clamp **1218**. As seen in FIG. **35**B, a first portion of a ramp, e.g., ramp **1230**B, can define teeth **1236** while a second portion **1238** of the ramp remains substantially smooth. Further, a straight portion **1240** of the sliding clamp **1218** adjacent to the teeth **1236** of the first portion of the ramp **1230**B can also define the teeth **1236**.

In addition to the teeth **1236** defined by the ramps **1230**A-**1230**D (and any adjacent straight portions), the sliding clamp **1218** can include other portions that define a plurality of teeth. In the example configuration shown in FIG. **35**B, the sliding clamp **1218** can include teeth **1242** to increase the torsional rotation resistance. As the fixation bolt **1216** (FIG. **30**) pulls the sliding clamp **1218** laterally, each set of teeth **1236**, **1242** can grip a bone pin, thereby increasing the locking force.

FIG. **36** depicts another example of a sliding clamp that can be used in accordance with various techniques of this disclosure. In contrast to the examples of sliding clamps depicted in FIGS. **30**, **34**A-**34**B, and **35**A-**35**B that had asymmetric designs, the sliding clamp **1218** of FIG. **36** includes a design that is symmetric about an axis **1244** extending along the length of the sliding clamp **1218**.

In the example symmetric configuration shown in FIG. **36**, the sliding clamp **1218** includes a plurality of pairs of ramps **1230**A-**1230**H, e.g., ramps **1230**A, **1230**E form a first pair of ramps, ramps **1230**B, **1230**F form a second pair of ramps, etc. Similar to the configuration shown above with respect to FIGS. **34**A and **34**B, the ramps **1230**A-**1230**H can include portions that define a plurality of teeth **1236**. The teeth **1236** can improve the torsional rotation resistance of the bone pins on the sliding clamp **1218**. A first portion of a ramp, e.g., ramp **1230**A, can define teeth **1236** while a second portion of the ramp remains substantially smooth. In addition, a straight portion of the ramp, e.g., ramp **1230**A, adjacent to the teeth **1236** of the first portion of the ramp **1230**A can also define the teeth **1236**. As the fixation bolt **1216** (FIG. **30**) pulls the sliding clamp laterally, the teeth **1236** can grip a bone pin, thereby increasing the locking force.

FIG. **37** depicts another example of a sliding clamp that can be used in accordance with various techniques of this disclosure. In contrast to the example sliding clamps described above, the sliding clamp **1218** of FIG. **37** defines four apertures (**1228**A-**1228**D) instead of two. The apertures **1228**A-**1228**D can define a plurality of pairs of ramps **1230**A-**1230**H. The configuration in FIG. **37** can improve rotational lock because the two ramps per aperture create three points of contact (two from the ramps and one on the bushing).

Like the example of a sliding clamp **1218** shown in FIG. **36**, the sliding clamp **1218** of FIG. **37** includes a design in which the apertures **1228**A-**1228**D are symmetric about an axis **1244** extending along the length of the sliding clamp **1218**. However, the sliding clamp **1218** of FIG. **37** does not define any teeth. Rather, the torsional resistance provided by the sliding clamp **1218** is a result of contact with a bone pin from each of the ramps in a pair, e.g., ramps **1230**A, **1230**E, and contact with a bushing (not depicted). This 3-point contact with a bone pin can provide sufficient forces to lock the bone pin in place.

It should be noted that any of the sliding clamps depicted in FIGS. **34**A-**37** can be configured without teeth.

FIG. **38** is a cross-sectional view of another example of a clamp assembly **1200**. In contrast to the sliding clamp **1218** described above, the clamp assembly **1200** can include a flexible plate **1248**, e.g., spring steel. The flexible plate **1248** can define curved notches at each of its ends that are configured to engage a respective bone pin **1212**, **1214** (notches **1250**A, **1250**B are shown in FIG. **39**).

When uncompressed, the flexible plate **1248** can assume a curved shape, as seen in FIG. **38**. When compressed by a fixation bolt **1216**, the flexible plate **1248** can flex and take on a more linear shape. As the flexible plate **1248** flexes, the bone pins **1212**, **1214** can frictionally engage with the portions of the flexible plate **1248** that define the curved notches to create a mechanical lock.

FIG. **39** is a top view of the flexible plate of FIG. **38**. The flexible plate **1248** includes first and second ends **1252**, **1254** that define respective curved notches 1250A, 1250B that are each configured to engage a bone pin to create a mechanical lock.

FIG. 40 is a perspective view of another example of a rod clamp assembly 1260. The rod clamp assembly 1260 of FIG. 40 can be used as an alternative to rod clamp assembly 606 and can form a portion of the rod assembly 506, which are described above with respect to FIGS. 7-10, for example. For purposes of conciseness, many of the components of rod assembly 506 will not be described in detail again.

Like the rod clamp assembly 606 of FIGS. 7-10, the rod clamp assembly 1260 of FIG. 40 can also be described as a split collar locking device. The rod clamp assembly 1260 can include a split clamp 1262 (or locking collar), a binding collar 1264 configured to be coaxially aligned with the spring clamp 1262, and a spring housing 1266. The split clamp 1262 can define a circular bore 1268 which is interrupted by a collar gap 1270. A screw 1271 can be received in a screw bore of the split clamp 1262 and adjust the size of the collar gap 1270. As described in more detail below, the spring housing 1266, e.g., a molded housing, can retain a spring (shown at 1274 in FIG. 41), which biases the binding collar 1264 downward against the split clamp 1262.

FIG. 41 is a cross-sectional side view of the rod clamp assembly 1260 of FIG. 40 in combination with a first rod 1272, where a second rod is slidably disposed within the first rod 1272, (see FIGS. 2 and 8). The rod clamp assembly 1260 can include the split clamp 1262, the binding collar 1264, the spring housing 1266, a spring 1274, a fulcrum 1276, and one or more protrusions, or tabs 1278, positioned about an exterior surface of the split clamp 1262, e.g., two tabs 1278.

When the split clamp 1262 is opened and slid over the first rod 1272, the one or more protrusions, or tabs 1278, can mate with one or more corresponding holes 1280 on the first rod 1272. The tabs 1278 can help retain the split clamp 1262 on the first rod 1272 without the use of an adhesive.

As mentioned above, the spring housing 1266 can retain the spring 1274, which biases the binding collar 1264 downward. The fulcrum 1276 can provide the reaction force that holds an end 1282 of the binding collar 1264 up to create a binding force with the second rod slidably disposed within the first rod 1272.

The design of the rod clamp assembly 1260 of FIG. 41 can advantageously eliminate several components of the design of the rod clamp assembly 606 of FIGS. 7-10. For example, the pin 622 shown in FIG. 8, which can connect the binding collar 624 to the locking collar 620, can be eliminated because the binding collar 1264 of FIG. 41 can be constrained by the binding effect with the rod 1272 as a result of the fulcrum 1276. This design change can allow the binding collar 1264 to be waterjet cut or stamped, rather than machined.

As another example, the spring 1274 can replace the spring 630 of FIG. 8, which is retained in the spring housing 1266. The use of the spring housing 1266 can allow the spring 1274 to be retained inside the split clamp 1262, e.g., molded, and can eliminate the retention pin 628 and the retainer 632 of FIG. 8.

Finally, as mentioned above, the use of one or more tabs 1278 can eliminate the need for a glue to retain the split clamp 1262 to the rod 1272. As a result of the simplification in assembly and the reduction in components, the design of FIGS. 40 and 41 can be less expensive to produce.

FIG. 42 is a perspective view of a portion of a rod assembly 1284 including the rod clamp assembly 1260 of FIG. 40. The rod assembly 1284 is similar to the rod assembly 506 of FIG. 7, with the exception of the rod clamp assembly 1260, and, for purposes of conciseness, will not be described again. As seen in FIG. 42, the rod clamp assembly 1260 can include a tab member 1286, which can be similar to the tab member 670 described above, e.g., with respect to FIG. 8. The presence of the tab member 1286 can keep a collar gap of the split clamp 1262 open, which allows the tubular member 1272 and an inner tubular member (e.g., inner tubular member 602 of FIG. 8) to axially move relative to one another in both directions, by preventing bore 1268 from clamping around the tubular members and provisionally locking the tubular members together.

FIG. 43 is an exploded view of a trocar assembly 1290. The trocar assembly 1290 can include a tissue sleeve 1292 that defines a lumen, a first grip 1294 that is affixed to an end 1296 of the tissue sleeve 1292, an obturator 1298 that can extend through an opening in the first grip 1294 and into the lumen of the tissue sleeve 1292, and a second grip 1300 that is affixed to an end 1302 of the obturator 1298. The trocar assembly 1290 can include an interlocking feature between the first grip 1294 of the tissue sleeve 1292 and the second grip 1300 of the obturator 1298 that can hold the assembly 1290 together, as seen in FIGS. 44A-44C and described below.

The obturator 1298 can allow a clinician to insert the trocar assembly 1290 through soft tissue to access a bone surface. Once the target location is reached, the obturator 1298 can be removed to expose the bone surface for insertion of a bone pin through the tissue sleeve 1292.

FIGS. 44A-44C are perspective views of the first grip and the second grip of the trocar assembly of FIG. 43. For purposes of conciseness, FIGS. 44A-44C will be described together.

The second grip 1300 can include a pair of grip wings 1304, 1306, which when grasped, can be used to rotate the second grip 1300. Further, the first grip 1294 and the second grip 1300 can be keyed to allow the grips 1294, 1300 to interlock. For example, the second grip 1300 can include a projection 1308 that can mate with a notch 1310 of the first grip 1294, e.g., a bayonet connector, which can lock the two grips 1294, 1300 together.

In some example configurations (not depicted), additional features can be included to further interlock the first grip 1294 and the second grip 1300. For example, spring locks, ball detents, interference fittings, threaded connections, and/or alternative bayonet connectors can be used to interlock the first grip 1294 and the second grip 1300.

As seen in FIGS. 44A-44C, the first grip 1294 and the second grip 1300 can be interlocked by rotating the grip wings 1304, 1306 until the projection 1308 is positioned within the notch 1310. Disengagement can be accomplished by rotating the grip wings 1304, 1306 in the opposite direction.

FIG. 45 is a perspective view of the trocar assembly 1290 of FIG. 43 in an interlocked position. The first grip 1294 is interlocked with the second grip 1300.

FIGS. 46A-46C are perspective views of another example of a first grip and a second grip that can be used with a trocar assembly. For purposes of conciseness, FIGS. 46A-46C will be described together.

As seen in FIGS. 46A-46C and in contrast to the design of FIGS. 44A-44C, each of the first grip 1294 and the second grip 1300 can include first and second grip wings. The first grip 1294 can include first and second grip wings 1312, 1314 and the second grip 1300 can include first and second grip wings 1302, 1304. Further, the first grip 1294 and the second grip 1300 can be keyed to allow the grips 1294, 1300 to interlock. For example, the second grip 1300 can include a projection **1308** that can mate with a notch **1310** of the first grip **1294**, e.g., a bayonet connector, which can lock the two grips **1294**, **1300** together.

FIG. **47** is a perspective view of a trocar assembly **1290** depicting the first and second grips of FIGS. **46**A-**46**C in an interlocked position. The first grip **1294** is interlocked with the second grip **1300**.

FIG. **48** is a top view of another example of a clamping assembly of the external fixation system. FIG. **49** is a perspective view of the clamping assembly of FIG. **48** with bone pins **1232**, **1234** depicted. For purposes of conciseness, FIGS. **48** and **49** will be described together. The clamping assembly **1400** of FIG. **48** includes a main clamp body **1402** that defines a plurality of holes, e.g., four holes **1404**A, **1404**B, **1404**C, **1404**D (collectively holes "**1404**"), that are positioned such that they are offset from a clamp hoop centerline **1406**, as seen in FIG. **48**, of a clamp hoop **1134** (or "clamp"). That is, in contrast to the clamping assembly **1102** of FIG. **22** where the main clamp body defines two holes that are centered about a clamp hoop centerline, the holes **1404** of the clamping assembly of FIG. **48** are biased away from the centerline **1406** such that holes **1404**B-**1404**D are successively further away from the centerline **1406**.

In some example configurations, the main clamp body **1402** can be similar to the main clamp body **1202** of FIG. **28** and can include a sliding clamp, e.g., sliding clamp **1218** of FIG. **28**. In some example configurations, the clamping assembly can include two clamp hoops, such as shown in FIG. **28**. In configurations with two clamp hoops (or "clamps"), the plurality of holes along the main clamp body would be similarly offset from a second clamp hoop centerline.

FIG. **50** is a perspective view of an example of an external fixation system, the system including two clamping assemblies of FIG. **48**, a rod assembly, and a plurality of bone pins. FIG. **51** is a side view of the external fixation system of FIG. **50**. For purposes of conciseness, FIGS. **50** and **51** will be described together. The example system **1408** of FIG. **50** includes a first clamping assembly **1400**A, a second clamping assembly **1400**B, and a rod assembly **506**. The rod assembly **506** extends between and connects the clamping assemblies **1400**A, **1400**B into the single system **1408**. The rod assembly **506** can include a rod clamp assembly **1260**, such as shown and described above with respect to FIGS. **40** and **41**.

Using the clamping assembly **1400** of FIG. **48** in the external fixation system **1408** of FIG. **50** can provide several advantages. For example, by shifting the bone pin holes **1232**, **1234** away from the clamp hoop centerline **1406** and toward the center of the rod assembly **506**, the bone pins of opposing clamps can initially be positioned closer at the fully collapsed state of the frame. In addition, the offset bone pin holes **1404** can allow longer tubular elements, e.g., tubular element **600**, to be used, which can allow greater expansion of the frame.

FIG. **52** is a cross-sectional view of an example of an expansion plug of a rod assembly, in accordance with this disclosure. Instead of including a long, radiopaque metal locking screw that extends substantially the length of a tubular element, such as shown at **604** in FIG. **8**, a rod assembly, such as shown at **1410** in FIG. **53**, can include a much shorter radiopaque metal expansion plug screw **1412** in combination with a radiolucent expansion plug **1414**, e.g., made of plastic. The expansion plug **1414** with protrusion **1416** can extend along length of the inner tubular element **602** and can cause the inner tubular element **602** to expand at its end. Using the radiolucent expansion plug **1414** can provide a clinician with better images, e.g., x-ray images, of the area of interest than using a long, radiopaque metal screw.

As seen in FIG. **52**, the expansion plug screw **1412** extends through a spherical portion **614** of a tube plug **610** and into one end of the expansion plug **1414**. The expansion plug screw **1412** can be secured within the expansion plug **1414** using a retention nut **1420**. When the expansion plug screw **1412** is turned, an expansion plug nut **1422** allows the expansion plug **1414** to translate along while the screw **1412** remains stationary. That is, instead of the expansion screw **1412** moving in and out as it is turned, turning the screw **1412** causes the expansion plug **1414** to move.

FIG. **53** is an exploded view of a rod assembly **1410** including the expansion plug **1414** of FIG. **52**. Many of the components of the rod assembly **1410** are similar to those shown and described above with respect to FIG. **8** and, as such, will not be described again. As seen in FIG. **53**, the rod assembly **1410** can include the expansion plug **1414**, the expansion screw **1412**, and the expansion plug nut **1422** of FIG. **52**. The expansion plug **1414** is configured to extend through the inner tubular element **602**. The expansion screw **1412** can be turned until the inner tubular member **602** has expanded sufficiently (via the protrusion **1416** of the expansion plug **1414**) to cause a first end **1424** of the inner tubular member **602** to fit tightly within outer tubular member **600**, and lock its position relative to outer tubular member **600**.

The rod assembly **1410** of FIG. **53** can also include a cable **1426**, e.g., a flexible, braided metal cable. The cable **1426** can attach to an end **1428** of the expansion plug **1414**, and can fit into a "lanyard button" (not depicted) that can attach into a spherical portion **614** on the other end of the expansion plug **1414**. The cable **1426** can act as a stopper mechanism to limit the inner and outer tubular element travel, and can prevent overexpansion so that the outer and inner tubular elements **600**, **602** do not separate before lockout. The cable **1426** can coil up inside the inner tubular element **602** when the frame is collapsed to the smallest length configuration, and can straighten as the frame is expanded.

FIG. **54** is a perspective view of an example of a hinged main clamp body **1430**. As seen in FIG. **54**, a clamp hoop **1432** is pivotally engaged to a main clamp body **1434** using a pin **1436** and a locking screw **1438**. In some example configurations, the main clamp body **1434** can be similar to the main clamp body **1202** of FIG. **28** and include a sliding clamp, e.g., sliding clamp **1218** of FIG. **28**.

The hinged design can provide several advantages. For example, the hinged design can allow a user to rotate the clamp hoop **1432** independent of the clamp body **1434**. In addition, the hinged design can allow the bone pins (not depicted) to be placed at nearly 90 degrees relative to the long axis of the tubular element of the frame (see FIG. **57**). The hinged joint can allow for a larger variation in overall frame length and more flexibility in bone pin placement. Instead of requiring a separate piece to accommodate bone pin placement that is parallel to the radial joint, the design of FIG. **54** can allow the clamp hoop **1432** to be rotated to allow equivalent pin placement without any separate parts or assembly.

FIGS. **55**A and **55**B are perspective views of a clamp hoop body **1440** and the main clamp body **1434** of FIG. **54**, respectively. For purposes of conciseness, FIGS. **55**A and **55**B will be described together. In FIG. **55**A, the clamp hoop body **1440** includes the clamp hoop **1432** and a first engagement portion **1442** that defines a first aperture **1444** and a second aperture **1446**. In FIG. **55**B, the main clamp body

1434 includes a second engagement portion **1448** that defines a third aperture **1450**. When aligned, the first and third apertures **1444**, **1450** are configured to receive the pin **1436** (FIG. **54**), which hingedly secures the clamp hoop body **1440** to the main clamp body **1434**. The clamp hoop body **1440** includes a first cylindrical bearing surface **1452** and the main clamp body **1434** includes a second cylindrical bearing surface **1454**, which frictionally engage one another. As described below, when tightened, the locking screw **1438** (FIG. **54**) forces the first cylindrical bearing surface **1452** and the second cylindrical bearing surface **1454** together to form a frictional fit.

FIG. **56** is a cross-sectional view of the example of the hinged main clamp body **1430** of FIG. **54**. The pin **1436** is the center of rotation **1456** about a hinge **1458** that allows the clamp hoop **1432** to rotate. The pin **1436** can define a hole **1457** in its center that allows the locking screw **1438** to extend through the clamp hoop body **1440** and through the pin **1436** and the second aperture **1446** of the first engagement portion **1442**. The pin **1436** and the locking screw **1438** can allow for polyaxial rotation about a spherical portion of a tube plug. In addition, the design of FIG. **56** allows for rotation about the pin **1436** to be locked out with a single screw, namely locking screw **1438**. The lock-out can be achieved as the screw **1438** "pinches" the first cylindrical bearing surface **1452** and the second cylindrical bearing surface **1454** together. In some examples, if additional contact is desired between the cylindrical bearing surfaces **1452**, **1454** to increase the lock, one or more protrusions, e.g., interlocking teeth, can be added to one or both of the interfacing cylindrical surfaces.

FIG. **57** is a perspective view of an external fixation system **1460**, secured to a radius of an arm **1462**. The system **1460** can include a rod assembly **506** extending between a first hinged main clamp body **1430**A and a second hinged main clamp body **1430**B. As seen in FIG. **57**, the hinged design of the first hinged main clamp body **1430**A can allow the clamp hoop **1430** to be rotated such that a line **1464** formed by the bone pins extending through the first hinged main clamp body **1430**A can form an angle with a longitudinal axis **1466** of the rod assembly **506** that can approach 90 degrees.

The systems disclosed herein may provide advantages over external fixation systems known in the art. For example, providing pre-assembled systems such as **500**, **800**, or **1100** which are anatomy-specific can reduce the number of parts or inventory necessary to perform an external fixation procedure, compared to systems which are provided as a comprehensive kit of loose parts. Also, having a pre-assembled system can minimize unanticipated disassembly during an external fixation procedure and during tightening and adjustment of the system. The pre-assembled system may therefore provide a low-stress user experience for the practitioner, for example, by eliminating tedious intraoperative assembly or unanticipated disassembly. Use of the pre-assembled systems disclosed herein also reduces or eliminates operating room or procedure time which, for other systems known in the art, is spent assembling a fixation system on the back table. The one-way locking mechanism may retain limb length during tightening and adjustment of the system without requiring constant distraction by the surgeon. The one-way locking mechanism contributes to ease of obtaining fracture reduction, and the provisional locking is secure enough to allow easy adjustment of the reduction while the system is provisionally locked. The removable tab member **670** provides quick conversion between the unlocked configuration and the locked configuration, allowing quick and efficient distraction and reduction. The systems disclosed herein can be applied to a patient by one or two practitioners, which may reduce the number of practitioners needed and overall procedure cost.

In addition to the embodiments shown herein to span the knee, ankle, and/or wrist joints, it is appreciated that principles taught herein may be applied to external fixators and fixation methods for other joints, including but not limited to the elbow, wrist, carpal, tarsal, phalanges, hip, sacrum, shoulder, cranium, and/or intervertebral joints. The technology disclosed herein may also be applied to external fixation and fixation methods for fractures rather than joints.

The apparatus disclosed herein may be made from low cost materials, such as aluminum and/or plastic, using low cost manufacturing techniques such as lathe and mill. In some embodiments, the system may be so inexpensive as to be single-use disposable. In this situation, there would be no re-processing or re-stocking fees charged to the owner of the apparatus.

It should be understood that the present system, kits, apparatuses, and methods are not intended to be limited to the particular forms disclosed. Rather, they are to cover all modifications, equivalents, and alternatives falling within the scope of the claims.

The claims are not to be interpreted as including means-plus- or step-plus-function limitations, unless such a limitation is explicitly recited in a given claim using the phrase(s) "means for" or "step for," respectively.

The term "coupled" is defined as connected, although not necessarily directly, and not necessarily mechanically.

The use of the word "a" or "an" when used in conjunction with the term "comprising" in the claims and/or the specification may mean "one," but it is also consistent with the meaning of "one or more" or "at least one." The term "about" means, in general, the stated value plus or minus 5%. The use of the term "or" in the claims is used to mean "and/or" unless explicitly indicated to refer to alternatives only or the alternative are mutually exclusive, although the disclosure supports a definition that refers to only alternatives and "and/or."

The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method or device that "comprises," "has," "includes" or "contains" one or more steps or elements, possesses those one or more steps or elements, but is not limited to possessing only those one or more elements. Likewise, a step of a method or an element of a device that "comprises," "has," "includes" or "contains" one or more features, possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. It is appreciated that various features of the above-described examples can be mixed and matched to form a variety of other alternatives. For example, a clamping body or assembly described for one system may be used with another system. Features of instrumentation from one example may be applied to instrumentation from another example. As such, the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The invention claimed is:

1. A clamp assembly for external fixation of a limb, the clamp assembly comprising:

a first clamp configured to connect to a first rod assembly, the first clamp having a centerline;

a main clamp body arranged offset with respect to the centerline and pivotally connected to the first clamp, the main clamp body having a longitudinal axis, the main clamp body comprising a plurality of holes along the longitudinal axis, each of the holes configured to receive a bone pin, and each of the holes being positioned successively further away from the centerline of the first clamp;

a sliding clamp connected to the main clamp body and extending along the longitudinal axis, the sliding clamp configured to move along the longitudinal axis and to secure the bone pin in place, the sliding clamp comprising at least one aperture with at least one set of teeth configured to secure the at least one bone pin in place; and

a fixation bolt coupled to and configured to actuate the sliding clamp.

2. The clamp assembly of claim **1**, wherein the fixation bolt extends into a side of the main clamp body and along the longitudinal axis.

3. The clamp assembly of claim **1**, wherein the sliding clamp is configured to secure the at least one bone pin against the main clamp body.

4. The clamp assembly of claim **1**, further comprising at least one bushing positioned within the at least one hole, wherein the sliding clamp configured to move along the longitudinal axis and to secure the at least one bone pin in place is configured to secure the at least one bone pin against the at least one bushing.

5. The clamp assembly of claim **1**, wherein the at least one aperture comprises at least one ramp portion having a slope, and wherein the at least one ramp portion is configured to secure the at least one bone pin in place.

6. The clamp assembly of claim **5**, wherein the at least one ramp portion comprises the set of teeth.

7. The clamp assembly of claim **1**, wherein the at least one set of teeth comprises first and second sets of the teeth, the first and second sets of teeth configured to secure the at least one bone pin in place.

8. The clamp assembly of claim **1**, wherein the sliding clamp comprises two apertures, and wherein the two apertures are symmetric about the longitudinal axis.

9. The clamp assembly of claim **1**, wherein the sliding clamp comprises four apertures, and wherein the four apertures are symmetric about the longitudinal axis.

10. The clamp assembly of claim **1**, further comprising:

a pin; and

a locking screw configured to extend through the first clamp, and wherein:

the first clamp includes a first engagement portion comprising a first aperture sized and shaped to receive the pin,

the main clamp body includes a second engagement portion comprising a second aperture sized and shaped to receive the pin,

the main clamp body is pivotally connected to the first clamp by the first engagement portion and the second engagement portion being aligned and by the pin extending through the first aperture and the second aperture,

the pin comprises a hole configured to receive the locking screw,

the first engagement portion comprises a first cylindrical bearing surface,

the second engagement portion comprises a second cylindrical bearing surface configured to engage the first cylindrical bearing surface, and

when the locking screw is tightened, the first and second cylindrical bearing surfaces engage one another.

11. The clamp assembly of claim **10**, wherein at least one of the first and second cylindrical bearing surfaces comprises at least one protrusion.

12. A clamp assembly for external fixation of a limb, the clamp assembly comprising:

a rod clamp configured to connect to a rod assembly, the rod clamp having a centerline;

a main clamp body pivotally connected to the rod clamp, the main clamp body having a longitudinal axis, the main clamp body comprising a plurality of holes disposed along the longitudinal axis, each of the holes configured to receive a bone pin, and each of the holes being positioned successively further away from the centerline of the rod clamp;

a sliding clamp connected to the main clamp body, the sliding clamp configured to slide along the longitudinal axis and to secure the bone pin in place, the sliding clamp comprising at least one aperture with at least one set of teeth configured to secure the at least one bone pin in place;

a fixation bolt coupled to the sliding clamp and configured to actuate the sliding clamp; and

a pin, wherein the first clamp includes a first engagement portion comprising a first aperture sized and shaped to receive the pin,

wherein the main clamp body includes a second engagement portion comprising a second aperture sized and shaped to receive the pin, and

wherein the main clamp body is pivotally connected to the rod clamp by the first engagement portion and the second engagement portion being aligned and by the pin extending through the first aperture and the second aperture.

13. The clamp assembly of claim **12**, further comprising at least one bushing positioned within the at least one hole, wherein the sliding clamp configured to slide along the longitudinal axis and to secure the at least one bone pin in place is configured to secure the at least one bone pin against the at least one bushing.

14. The clamp assembly of claim **12**, wherein the at least one aperture comprises at least one ramp portion having a slope, and wherein the at least one ramp portion is configured to secure the at least one bone pin in place.

15. The clamp assembly of claim **14**, wherein the at least one ramp portion comprises the set of teeth.

16. The clamp assembly of claim **12**, wherein the at least one set of teeth comprises first and second sets of the teeth, the first and second sets of teeth configured to secure the at least one bone pin in place.

17. The clamp assembly of claim **12**, further comprising a locking screw configured to extend through the first clamp, and wherein:

the pin comprises a hole configured to receive the locking screw,

the first engagement portion comprises a first cylindrical bearing surface,

the second engagement portion comprises a second cylindrical bearing surface configured to engage the first cylindrical bearing surface, and

when the locking screw is tightened, the first and second cylindrical bearing surfaces engage one another.

18. The clamp assembly of claim **17**, wherein at least one of the first and second cylindrical bearing surfaces comprises at least one protrusion.

19. clamp assembly for external fixation of a limb, the clamp assembly comprising:

a first clamp configured to connect to a first rod assembly, the first clamp having a centerline;

a main clamp body pivotally connected to the first clamp, the main clamp body having a longitudinal axis, the main clamp body comprising a plurality of holes along the longitudinal axis, each of the holes configured to receive a bone pin, and each of the holes being positioned successively further away from the centerline of the first clamp;

a sliding clamp connected to the main clamp body and extending along the longitudinal axis, the sliding clamp configured to move along the longitudinal axis and to secure the bone pin in place, the sliding clamp comprising at least one aperture with at least one set of teeth configured to secure the at least one bone pin in place;

a fixation bolt coupled to and configured to actuate the sliding clamp; and

a pin, wherein the first clamp includes a first engagement portion comprising a first aperture sized and shaped to receive the pin,

wherein the main clamp body includes a second engagement portion comprising a second aperture sized and shaped to receive the pin, and

wherein the main clamp body is pivotally connected to the first clamp by the first engagement portion and the second engagement portion being aligned and by the pin extending through the first aperture and the second aperture.

20. The clamp assembly of claim **19**, further comprising at least one bushing positioned within the at least one hole, wherein the sliding clamp configured to move along the longitudinal axis and to secure the at least one bone pin in place is configured to secure the at least one bone pin against the at least one bushing.

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